DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-54

DATE: **August 14, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes -** Issuance of Revisions to Interpretive Guidance at F Tag 441, as Part of Appendix PP, State Operations Manual (SOM), and Training Materials

Memorandum Summary

- Revisions have been made to Guidance to Surveyors at F Tag 441 in Appendix PP of SOM concerning Infection Control.
- Tags F442, 443, 444, and 445 are deleted and the regulatory language and guidance moved to F441.
- A training document with speaker notes for Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) and State Survey Agencies (SAs) to use to train surveyors on this revision to F tag 441 in the SOM is included in this memorandum.
- Power point slides will be issued to ROs and SAs under a separate communication.

We made changes to surveyor guidance for Infection Control in Appendix PP of the SOM. The changes will provide clarification to nursing home surveyors when determining compliance with the regulatory requirements for infection control. The regulatory language will remain unchanged.

We deleted F Tags 442, 443, 444, and 445 which contained language about preventing the spread of infections, and incorporated the guidance into F Tag 441.

This revision will be implemented on September 30, 2009. At that time, a final copy of this new guidance will be available at http://www.cms.hhs.gov/Transmittals/ and ultimately incorporated into Appendix PP of the SOM.

Here, we are providing an advance copy of the revised guidance. All new language is presented in red and italics. Also attached to this memorandum are training materials for the revised Tag. This training packet is to be used to assure that all surveyors who survey nursing homes are trained in the revised guidance by the implementation date. These materials were presented and discussed in a teleconference with ROs on August 3, 2009. We encourage training to be conducted in person with group discussion to optimize learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. This guide may also be used to communicate with provider groups and other stakeholders.

Enclosed with this memorandum are the following files:

- Transmittal Sheet describing changes;
- Advance copy of surveyor guidance revision; and
- Guidance Training Instructor Guide in Microsoft Word

PowerPoint training slides will be made available to ROs and SAs under a separate communication.

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

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

Effective Date: September 30, 2009. The State Agency should disseminate this information within 30 days of the date of this memorandum.

Training: The training materials should be distributed immediately to all SA training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **Date:**

SUBJECT: Revisions to Appendix PP – "Interpretive Guidelines for Long-Term Care Facilities F tag F441"

I. SUMMARY OF CHANGES: This instruction combines F tags 441, 442, 443, 444 and 445, and incorporates the guidance into F441.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F tag 441 to include all of §483.65(a)(b)(c)
D	Appendix PP/F tag 442
D	Appendix PP/F tag 443
D	Appendix PP/F tag 444
D	Appendix PP/F tag 445

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

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

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

Advance Copy

F441

§483.65 Infection Control

(Rev)

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

(1) Investigates, controls, and prevents infections in the facility;
(2) Decides what procedures, such as isolation, should be applied to an individual resident; and
(3) Maintains a record of incidents and corrective actions related to infections.

§483.65(b) Preventing Spread of Infection

(1) When the Infection Control Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.
(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.
(3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

§483.65(c) Linens

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

INTENT: (F441) 42CFR 483.65 Infection Control

The intent of this regulation is to assure that the facility develops, implements, and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility. The program will:

- *Perform surveillance and investigation to prevent, to the extent possible, the onset and the spread of infection;*
- *Prevent and control outbreaks and cross-contamination using transmission- based precautions in addition to standard precautions;*
- *Use records of infection incidents to improve its infection control processes and outcomes by taking corrective actions, as indicated;*
- *Implement hand hygiene (hand washing) practices consistent with accepted standards of practice, to reduce the spread of infections and prevent cross-contamination; and*
- *Properly store, handle, process, and transport linens to minimize contamination.*

DEFINITIONS

Definitions are provided to clarify terminology or terms related to infection control practices in nursing homes.

- ***"Airborne precautions"*** *refers to actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.*[i]
- ***"Alcohol-based hand rub"*** *(ABHR) refers to a 60-95 percent ethanol or isopropyl-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.*
- ***"Antifungal"*** *refers to a medication used to treat a fungal infection such as athlete's foot, ringworm or candidiasis.*
- ***"Anti-infective"*** *refers to a group of medications used to treat infections.*
- ***"Antiseptic hand wash"*** *is "washing hands with water and soap or other detergents containing an antiseptic agent."*[ii]
- ***"Cohorting"*** *refers to the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents). During outbreaks, healthcare personnel may be assigned to a cohort of residents to further limit opportunities for transmission (cohorting staff).*
- ***"Colonization"*** *refers to the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.*
- ***"Communicable disease"*** *(also known as [a.k.a.] "Contagious disease") refers to an infection transmissible (as from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (as by a vector).*
- ***"Community associated infections"*** *(formerly "Community Acquired Infections") refers to infections that are present or incubating at the time of admission, or generally develop within 72 hours of admission.*
- ***"Contact precautions"*** *are measures that are "intended to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct or indirect contact with the resident or the resident's environment."*[iii]
- ***"Droplet precautions"*** *refers to actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.*[iv]

- ***"Hand hygiene"*** *is a general term that applies to washing hands with water and either plain soap or soap/detergent containing an antiseptic agent; or thoroughly applying an alcohol-based hand rub (ABHR).*
- ***"Hand washing"*** *refers to washing hands with plain (i.e., nonantimicrobial) soap and water.*
- ***"Health care associated infection [HAI]"*** *(a.k.a. "nosocomial" and "facility-acquired" infection) refers to an infection that generally occurs after 72 hours from the time of admission to a health care facility.*
- ***"Infection"*** *refers the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc).*
- ***"Infection prevention and control program"*** *refers to a program (including surveillance, investigation, prevention, control, and reporting) that provides a safe, sanitary and comfortable environment to help prevent the development and transmission of infection.*
- ***"Infection preventionist (IP)"*** *(a.k.a. infection control professional) refers to a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired additional training in infection control.*
- ***"Isolation"*** *refers to the practices employed to reduce the spread of an infectious agent and/or minimize the transmission of infection.*
- ***"Isolation precautions"*** *see "Transmission-Based Precautions"*
- ***"Medical waste"*** *refers to any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining to, or in the production or testing of biologicals (e.g., blood-soaked bandages, sharps).*
- ***"Methicillin resistant staphylococcus aureus (MRSA)"*** *refers to Staphylococcus aureus bacteria that are resistant to treatment with semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).*
- ***"Multi-Drug resistant organisms (MDROs)"*** *refers to microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents.*[v]
- ***"Outbreak"*** *is the occurrence of more cases of a particular infection than is normally expected, the occurrence of an unusual organism, or the occurrence of unusual antibiotic resistance patterns.*[vi]
- ***"Personal protective equipment" (PPE)*** *refers to protective items or garments worn to protect the body or clothing from hazards that can cause injury.*
- ***"Standard precautions"*** *(formerly "Universal Precautions") refers to infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard Precautions is a combination and expansion of Universal Precautions and Body Substance Isolation (a practice of isolating all body substances such as blood, urine, and feces).*[vii]
- ***"Surveillance"*** *refers to the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.*
- ***"Transmission-based precautions"*** *(a.k.a. "Isolation Precautions") refers to the actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections.*

- ***"Vancomycin resistant enterococcus (VRE)"*** *refers to enterococcus that has developed resistance to vancomycin.*

OVERVIEW

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals. Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of $673 million to $2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

It is estimated that an average of 1.6 to 3.8 infections per resident occur annually in nursing homes. Urinary tract, respiratory (e.g., pneumonia and bronchitis), and skin and soft tissue infections (e.g., pressure ulcers) represent the most common endemic infections in residents of nursing homes.[viii] *Other common infections include conjunctivitis, gastroenteritis, and influenza.*[ix]

Confirming and managing an infectious outbreak can be costly and time consuming. An effective facility-wide infection prevention and control program can help to contain costs and reduce adverse consequences. An effective program relies upon the involvement, support, and knowledge of the facility's administration, the entire interdisciplinary team, residents, and visitors.

Critical aspects of the infection prevention and control program include recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay, as well as following recognized infection control practices while providing care (e.g., hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents). It is important that residents' conditions be reassessed because older adults may have coexisting diseases that complicate the diagnosis of an infection (e.g., joint degeneration vs. infectious arthritis, COPD versus pneumonia), and they may also have atypical or non-specific signs and symptoms related to infections, such as altered mental status, function or behavior, and impaired fever response.

Because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

NOTE: *It is important that all infection prevention and control practices reflect current CDC guidelines.*

INFECTION PREVENTION AND CONTROL PROGRAM

An effective infection prevention and control program is necessary to control the spread of infections and/or outbreaks.

Program Development and Oversight

Program development and oversight emphasize the prevention and management of infections. Program oversight involves establishing goals and priorities for the program, planning, and implementing strategies to achieve the goals, monitoring the implementation of the program (including the interdisciplinary team's infection control practices), and responding to errors, problems, or other identified issues. Additional activities involved in program development and oversight may include but are not limited to:

- *Identifying the staff's roles and responsibilities for the routine implementation of the program as well as in case of an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack;*
- *Developing and implementing appropriate infection control policies and procedures, and training staff on them;*
- *Monitoring and documenting infections, including tracking and analyzing outbreaks of infection as well as implementing and documenting actions to resolve related problems;*
- *Defining and managing appropriate resident health initiatives, such as:*
  - *The immunization program (influenza, pneumonia, etc); and*
  - *Tuberculosis screening on admission and following the discovery of a new case, and managing active cases consistent with State requirements;*
- *Providing a nursing home liaison to work with local and State health agencies; and*
- *Managing food safety, including employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.*

The facility identifies personnel responsible for overall program oversight, which may involve collaboration of the administrator, the medical director or his/her designee, the director of nursing, and other appropriate facility staff as needed. This group may define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program. The group communicates the findings from collecting and analyzing data to the facility's staff and management, and directs changes in practice based on identified trends, government infection control advisories, and other factors.

Components of an Infection Prevention and Control Program

An effective infection prevention and control program incorporates, but is not limited to, the following components:

- *Policies, procedures, and practices which promote consistent adherence to evidence-based infection control practices;*
- *Program oversight including planning, organizing, implementing, operating, monitoring, and maintaining all of the elements of the program and ensuring that the facility's interdisciplinary team is involved in infection prevention and control;*

- *Infection preventionist, a person designated to serve as coordinator of the infection prevention and control program;*
- *Surveillance, including process and outcome surveillance, monitoring, data analysis, documentation and communicable diseases reporting (as required by State and Federal law and regulation);*
- *Education, including training in infection prevention and control practices, to ensure compliance with facility requirements as well as State and Federal regulation; and*
- *Antibiotic review including reviewing data to monitor the appropriate use of antibiotics in the resident population.*

Examples of activities related to the Infection Prevention and Control Program may include but are not limited to:

- *Undertaking process and/or outcome surveillance activities to identify infections that are causing, or have the potential to cause an outbreak;*
- *Conducting data analysis to help detect unusual or unexpected outcomes and to determine the effectiveness of infection prevention and control practices;*
- *Documenting observations related to the causes of infection and/or infection trends; and*
- *Implementing measures to prevent the transmission of infectious agents and to reduce risks for device and procedure-related infections.*

Policies and Procedures

Policies and procedures are the foundation of the facility's infection prevention and control program. Policies and procedures are reviewed periodically and revised as needed to conform to current standards of practice or to address specific facility concerns.

Written policies establish the program's expectations and parameters. For example, policies may specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease.

Procedures guide the implementation of the policies and performance of specific tasks. Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

Infection Preventionist (IP)

A facility may designate an IP to serve as the coordinator of an Infection Prevention and Control Program. Responsibilities may include collecting, analyzing, and providing infection data and trends to nursing staff and health care practitioners; consulting on infection risk assessment,

prevention, and control strategies; providing education and training; and implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control and Prevention..

Surveillance

Essential elements of a surveillance system include use of standardized definitions and listings of the symptoms of infections, use of surveillance tools such as infection surveys and data collection templates, walking rounds throughout the facility,[x] identification of segments of the resident populations at risk for infection, identification of the processes or outcomes selected for surveillance, statistical analysis of data that can uncover an outbreak, and feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Two types of surveillance (process and outcome) can be implemented in facilities.

Process Surveillance

Process surveillance reviews practices directly related to resident care[x] in order to identify whether the practices comply with established prevention and control procedures and policies based on recognized guidelines. Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene,[xi] and the use and disposal of gloves. Process surveillance determines, for example, whether the facility:

- *Minimizes exposure to a potential source of infection;*
- *Uses appropriate hand hygiene prior to and after all procedures;[xii]*
- *Ensures that appropriate sterile techniques are followed; for example, that staff:*
    - *Use sterile gloves, fluids, and materials, when indicated,[xiii] depending on the site and the procedure;[xiv]*
    - *Avoid contaminating sterile procedures;[xv] and*
    - *Ensure that contaminated/non-sterile items are not placed in a sterile field.*
- *Uses Personal Protective Equipment (PPE) when indicated;[xvi]*
- *Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and*
- *Uses single-use medication vials and other single use items appropriately (proper disposal after every single use).[xvii]*

Outcome Surveillance

In contrast to process surveillance, outcome surveillance is designed to identify and report evidence of an infection. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections. The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends. Other sources of relevant data may include antibiotic orders, laboratory antibiograms (antibiotic susceptibility profiles), medication regimen review

reports, and medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.[xviii] *The facility's program should choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.*

Documentation

Facilities may use various approaches to gathering, documenting, and listing surveillance data. The facility's infection control reports describe the types of infections and are used to identify trends and patterns. Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

It is important that the infection prevention and control program define how often and by what means surveillance data will be collected, regardless of whether the facility creates its own forms, purchases preprinted forms, or uses automated systems.

Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance. The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents are monitored for current infections and infection risks.

Data Analysis

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home. Comparing current infection control surveillance data (including the incidence or prevalence of infections and staff practices) to past data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues. The facility can then evaluate whether it needs to change processes or practices to enhance infection prevention and minimize the potential for transmission of infections.

It is important that surveillance reports be shared with appropriate individuals including, but not limited to, the director of nursing and medical director. In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with State and local health department requirements for reporting communicable diseases.

Education

Both initial and ongoing infection control education help staff comply with infection control practices. Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.[xix] *In addition to education regarding general infection control principles, some infection control training is discipline and task specific (e.g., insertion of urinary catheters, suctioning, intravenous care or blood glucose monitoring). Follow-up competency evaluations identify staff compliance.*

Essential topics of infection control training include, but are not limited to routes of disease transmission, hand hygiene, sanitation procedures, MDROs, transmission-based precaution techniques, and the federally required OSHA education.

Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program. It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications. As part of the medication regimen review, the consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the director of nursing and the attending physician. See the Guidance at §483.65, F tag 329 regarding use of a medication without adequate indication for use and at §483.65, F tag 428 regarding medication regimen review.

PREVENTING THE SPREAD OF INFECTION

Factors Associated with the Spread of Infection in Nursing Homes

Many factors contribute to a substantial severity and frequency of infections and infectious diseases in nursing homes. These infections can arise from individual or institutional factors, or both. Modes of transmission of infection include but are not limited to:

a. *Contact;*
b. *Droplet; and*
c. *Airborne.*

Individual factors

Examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents include, but are not limited to the following:

- *Medications affecting resistance to infection such as corticosteroids and chemotherapy;*

- *Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);*
- *Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);*
- *Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);*
- *Complications from invasive diagnostic procedures such as skin or bloodstream infections;*
- *Impaired responses to infection (e.g., cell mediated responses); and*
- *Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).*

Institutional factors

In addition to individual factors, institutional factors may also facilitate transmission of infections among residents, including but not limited to:

- *Pathogen exposure in shared communal living space (e.g., handrails and equipment);*
- *Common air circulation;*
- *Direct/indirect contact with health care personnel/visitors/other residents;*
- *Direct/indirect contact with equipment used to provide care; and*
- *Transfer of residents to and from hospitals or other settings.*

Residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- *Improper hand hygiene;*
- *Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents); and*
- *Improper food handling.*

Direct Transmission (Person to Person)

Direct transmission occurs when microorganisms are transferred from an infected/colonized person to another person. Contaminated hands of healthcare personnel are often implicated in direct contact transmission. Agents that can be transmitted by direct contact include, but are not limited to MRSA, VRE, and Influenza.

Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object. The following are examples of opportunities for indirect contact.

- *Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents; and*
- *Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and Clostridium difficile). Indirect contact may occur through toilets and bedpans. Examples of illnesses spread via a fecal-oral route include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.*

Reducing and/or preventing infections through indirect contact requires the decontamination (i.e., cleaning, sanitizing, or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices. The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices.

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical and noncritical.[xx] *This includes:*

- *Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures;*[xx]

- *Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA-approved chemo sterilizer agent, or they may be sterilized; and*

- *Non-critical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.*

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Devices labeled by the manufacturer for single use are never to be reused, even if they are reprocessed.

Prevention and Control of Transmission of Infection

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin to skin) or indirect contact (e.g., via air, water, inanimate objects). Healthcare

personnel and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms. Another potential challenge is that the transmission of infectious organisms within the facility may be facilitated by inadequate hand hygiene facilities, rinsing bed pans in inappropriate places (e.g., resident's sink), or inappropriate placement of colonized or infected residents (e.g., sharing a bathroom with a non-infected resident).

Airborne transmission can occur by inhaling pathogenic droplet nuclei (e.g., M Tuberculosis). Contaminated environmental surfaces are also potential reservoirs for infections. Infections caused by bacteria and viruses are especially common. Clostridium difficile can live on inanimate surfaces for up to five months[xxi] while the hepatitis B virus can last up to a week[xxii] and the influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours.[xxiii]

The appropriate disposal of waste helps minimize the potential transmission of infections. It is important for the facility to monitor safe handling of blood and body fluids and the disposal of contaminated waste.

General Approaches to Prevention and Control

A facility's infection control practices are important to preventing the transmission of infections. Infection control precautions used by the facility include two primary tiers: "Standard Precautions" and "Transmission-Based Precautions."

Standard Precautions

Standard precautions are based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard precautions are intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of standard precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures should be used in each resident interaction.

Standard precautions include but are not limited to hand hygiene, safe injection practices, the proper use of PPE (e.g., gloves, gowns, and masks), resident placement, and care of the environment, textiles, and laundry. Also, equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment, and properly clean and disinfect or sterilize reusable equipment before use on another resident).[xxiv] In addition to proper hand hygiene, it is important for staff to use appropriate protective equipment as a barrier to exposure to any body fluids (whether known to be infected or not). For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections. Standard precautions are also intended to protect residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care.

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g., sharps containers, biohazard bags, etc.), and the environment is cleaned using germicidal agents to reduce the risk of transmission of infection.

Hand Hygiene

Hand hygiene continues to be the primary means of preventing the transmission of infection. The following is a list of some situations that require hand hygiene:

- *When coming on duty;*
- *When hands are visibly soiled (hand washing with soap and water);Before and after direct resident contact (for which hand hygiene is indicated by acceptable professional practice);*
- *Before and after performing any invasive procedure (e.g., fingerstick blood sampling);*
- *Before and after entering isolation precaution settings;*
- *Before and after eating or handling food (hand washing with soap and water);*
- *Before and after assisting a resident with meals (hand washing with soap and water);*
- *Before and after assisting a resident with personal care (e.g., oral care, bathing);*
- *Before and after handling peripheral vascular catheters and other invasive devices;*
- *Before and after inserting indwelling catheters;*
- *Before and after changing a dressing;*
- *Upon and after coming in contact with a resident's intact skin, (e.g., when taking a pulse or blood pressure, and lifting a resident);*
- *After personal use of the toilet (hand washing with soap and water);*
- *Before and after assisting a resident with toileting (hand washing with soap and water);*
- *After contact with a resident with infectious diarrhea including, but not limited to infections caused by norovirus, salmonella, shigella, and C. difficile (hand washing with soap and water);*
- *After blowing or wiping nose;*
- *After contact with a resident's mucous membranes and body fluids or excretions;*
- *After handling soiled or used linens, dressings, bedpans, catheters and urinals;*

- *After handling soiled equipment or utensils;*
- *After performing your personal hygiene (hand washing with soap and water);*
- *After removing gloves or aprons; and*
- *After completing duty.*

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections. It is necessary for staff to have access to proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods. Alcohol based hand rubs (ABHR) cannot be used in place of proper hand washing techniques in a food service setting.[xxv]

Recommended techniques for washing hands with soap and water include wetting hands first with clean, running warm water, applying the amount of product recommended by the manufacturer to hands, and rubbing hands together vigorously for at least 15 seconds covering all surfaces of the hands and fingers; then rinsing hands with water and drying thoroughly with a disposable towel; and turning off the faucet on the hand sink with the disposable paper towel.

Except for situations where hand washing is specifically required, antimicrobial agents such as ABHR are also appropriate for cleaning hands and can be used for direct resident care. Recommended techniques for performing hand hygiene with an ABHR include applying product to the palm of one hand and rubbing hands together, covering all surfaces of hands and fingers, until the hands are dry. In addition, gloves or the use of baby wipes are not a substitute for hand hygiene.

Other Staff-Related Preventive Measures

Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease. It is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.

It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. Wearing intact disposable gloves in good condition and that are changed after each use helps reduce the spread of microorganisms. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) while in the kitchen areas to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended by the FDA that dietary staff keep jewelry to a minimum and remove or cover hand jewelry when handling food.[xxvi]

Transmission-based Precautions

Transmission-based precautions are used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission. In nursing homes, it is appropriate to individualize

decisions regarding resident placement (shared or private), balancing infection risks with the need for more than one occupant in a room, the presence of risk factors that increase the likelihood of transmission, and the potential for adverse psychological impact on the infected or colonized resident.[xxvii]

It is essential both to communicate Transmission-based precautions to all health care personnel, and for personnel to comply with requirements. Pertinent signage (i.e., isolation precautions) and verbal reporting between staff can enhance compliance with transmission-based precautions to help minimize the transmission of infections within the facility.

It is important to use the standard approaches, as defined by the CDC for transmission-based precautions: airborne, contact, and droplet precautions.[xxviii] *The category of transmission-based precaution determines the type of PPE to be used. Communication (e.g., verbal reports, signage) regarding the particular type of precaution to be utilized is important. When transmission-based precautions are in place, PPE should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of transmission-based precaution employed.*

Transmission-based precautions are maintained for as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others. Maintaining isolation longer than necessary may adversely affect psychosocial well-being. The facility should document in the medical record the rationale for the selected transmission-based precautions.

Airborne Precautions

Airborne precautions prevent the transmission of organisms that remain infectious when suspended in the air (e.g., varicella zoster (shingles) and M. tuberculosis). Resident health activities related to infection control include tuberculosis (TB) screening and management of active cases, consistent with State requirements. Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity. Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed. In cases when AIIR is required it is important for the facility to have a plan in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.

Personnel caring for residents on airborne precautions should wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.[xxix] *Depending on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.*

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact. Contact precautions require the use of appropriate PPE,

including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room the PPE is removed and hand hygiene is performed.

Depending on the situation, options for residents on contact precautions may include the following: a private room, cohorting, or sharing a room with a roommate with limited risk factors (e.g., without indwelling devices, without pressure ulcers and not immunocompromised).

Droplet Precautions

In contrast to contact transmission, respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient. Since this generally occurs at close proximity, facial protection is necessary. Respiratory droplets are generated when an infected person coughs, sneezes, or talks; or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.[xxx] *Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.*

The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[xxxi] *In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances. Masks are to be used within approximately 6 to 10 feet of a resident or upon entry into a resident's room with respiratory droplet precautions. Residents with droplet precautions are placed in either a private room, cohorted, or share a room with a roommate with limited risk factors.*

Implementation of Transmission-Based Precautions

It is important that facility staff clearly identify the type of precautions and the appropriate PPE to be used in the care of the resident. PPE should be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

It is not always possible to identify prospectively residents needing transmission-based precautions. The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.[xxxii] *The use of appropriate transmission-based precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.*

Safe Water Precautions

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water (<500 CFU/mL per heterotrophic plate count).

HANDLING LINENS TO PREVENT AND CONTROL INFECTION TRANSMISSION

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission. If the facility handles all used linen as potentially contaminated (i.e., using standard precautions), no additional separating or special labeling of the linen is recommended. No special precautions (i.e., double bagging) or categorizing is recommended for linen originating in isolation rooms. Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances. If standard precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is important.

For the routine handling of contaminated laundry, minimum agitation is recommended, to avoid the contamination of air, surfaces, and persons. The risk of environmental contamination may be reduced by having personnel bag or contain contaminated linen at the point of use, and not sorting or pre-rinsing in resident care areas.

It is important that laundry areas have hand washing facilities and products, as well as appropriate PPE (i.e., gloves and gowns) available for workers to wear while sorting linens. Laundry equipment should be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system. It is recommended that damp linen is not left in machines overnight.

Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160ºF (71ºC) for 25 minutes.[xxxiii] *Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.*[xxxiv]

If laundry chutes are used, it is recommended that they are properly designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute).

If linen is sent off to a professional laundry, the facility should obtain an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport.

Standard mattresses and pillows can become contaminated with body substances during resident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming

contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. Therefore it is recommended that mattress covers with tears or holes be replaced. It is recommended that moisture resistant mattress covers be cleansed and disinfected between residents with an EPA approved germicidal detergent to help prevent the spread of infections, and fabric mattress covers should be laundered between residents. Pillow covers and washable pillows should be laundered in a hot water laundry cycle between residents or when they become contaminated with body substances. Discarding mattresses if fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.[xxxv]

RECOGNIZING AND CONTAINING OUTBREAKS

It is important that facilities know how to recognize and contain infectious outbreaks. An outbreak is typically one or more of the following:[xxxvi]

- *One case of an infection that is highly communicable;*
- *Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation; or*
- *Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.*

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it. State health departments offer guidance and regulations regarding responding to and reporting outbreaks. This information is often received in advance of an outbreak and included in the infection prevention and control program. Plans for containing outbreaks usually include efforts to prevent further transmission of the infection while considering the needs of all residents and staff.[XXXVI]

PREVENTING SPREAD OF ILLNESS RELATED TO MDROs

MDROs found in facilities include but are not limited to MRSA, VRE, and clostridium difficile (C. difficile). Transmission-based precautions are employed for residents who are actively infected with multi-drug resistant organisms. Aggressive infection control measures and strict compliance by healthcare personnel can help minimize the spread of MDROs to other susceptible individuals.[xxxvii]

Staphylococcus is a common cause of infections in hospitals and nursing homes, and increasingly in the community. Common sites of MRSA colonization include the rectum, perineum, skin and nares.[xxxviii] *Colonization may precede or endure beyond an acute infection. MRSA is transmitted person-to-person (most common), on inanimate objects and through the air.*

MRSA infection is commonly treated with vancomycin, which in turn can lead to increased enterococcus antibiotic resistance. Therefore, preventing infection with MRSA and the limited

use of antibiotics for individuals who are only colonized can also help prevent the development of VRE. Enterococcus is an organism that normally occurs in the colorectal tract. VRE infections have been associated with prior antibiotic use.

C. difficile is a bacterial species of the genus clostridium, which are gram-positive, anaerobic, spore-forming rods (bacilli). The organism normally lives benignly in the colon in spore form. When antibiotic use eradicates normal intestinal flora, the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever. More severe cases can lead to additional complications such as intestinal damage and severe fluid loss. Treatment options include stopping antibiotics and starting specific anticlostridial antibiotics, e.g., metronidazole or oral vancomycin. If a resident has diarrhea due to C. difficile, large numbers of C. difficile organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Contact precautions are instituted for residents with symptomatic C. difficile infection. Thorough hand washing with soap and water after caring for the resident reduces the risk of cross-transmission. Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents.

C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to six months. Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism.[xxxix] Cleaning equipment used for residents with C. difficile with a 1:10 dilution of sodium hypochlorite (one part water to nine parts bleach) will also reduce the spread of the organism. Once mixed, the solution is effective for 24 hours.

PREVENTING INFECTIONS RELATED TO THE USE OF SPECIFIC DEVICES

Intravascular catheters are used widely to provide vascular access, and are increasingly seen in nursing homes. While providing such access, they may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis.

Central venous catheters (CVCs) have also been associated with infectious complications. Other catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to central venous catheters for only the primary purpose may help reduce the risk of infection. Consistent use of appropriate infection control measures when caring for residents with vascular access catheters reduces the risk for catheter-related infections.[xl] Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as peripherally inserted central catheter lines, and midline access catheters. Activities to reduce infection risk includes surveillance such as observation of insertion sites, routine dressing changes, use of appropriate PPE and hand hygiene during the care and treatment of residents with venous catheters, and review of the resident for clinical evidence of infection.[XL] It is important that practices reflect the most current CDC guidelines.

ENDNOTES

INVESTIGATIVE PROTOCOL FOR INFECTION CONTROL

Objectives

- *To determine if the facility has an infection prevention and control program that prevents, investigates, and controls infections in the facility, and determines appropriate procedures to be applied to a resident with an infection;*
- *To determine if the facility has a program that collects information regarding infections acquired in the facility, analyzes the information and develops a plan of action to prevent further infections;*
- *To determine if staff practices are consistent with current infection control principles and prevent cross-contamination (e.g., laundry and hand hygiene practices); and*
- *To determine whether staff with communicable disease or open lesions are prohibited, as appropriate, from direct contact with the resident.*

Use

Use this protocol to investigate compliance at F441 for every initial certification and recertification survey. In addition, use this protocol on revisit or abbreviated surveys (complaint investigations) when indicated.

Procedures

The surveyor(s), throughout the survey, should conduct the following observations, interviews and record reviews. In addition the surveyor(s) should also review the facility's infection control policies, procedures, as well as documentation of staff training and, as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.

1. Observations

Observe various disciplines (nursing, dietary, and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures. Observe, for example, whether:

- *Linens are handled, processed, transported, and stored to prevent contamination and the transmission of infection;*
- *Employees exhibit overt signs of illness or communicable disease that have the potential to transmit disease (e.g., cold symptoms, infected, open lesions on hands) and if present, whether they are prohibited from contact with the resident or the resident's food;*
- *Staff and visitors adhere to precautions and related processes, including the use of PPE;*

- *Precautions/accommodations are in place and followed (as recommended, e.g., gowns, singles rooms or adequate space between residents, exclusion from group activities, etc.) for residents with potentially transmissible infections;*

- *Staff utilize appropriate precautions when residents on special precautions are permitted out of their rooms,(e.g., mask on resident with TB in the halls, wound drainage contained); and*

- *Staff involved in the care and management of residents with special needs, e.g., urinary catheters (also note characteristics of urine, which may indicate potential infection), wound care, respiratory treatments, and residents on ventilators, receiving IVs, or with tracheotomies follow current accepted infection control standards of practice.*

Also, observe residents for signs and symptoms of potential infection, such as:

- *Elevated respiratory rate or labored breathing, coughing, congestion;*

- *Vomiting or loss of appetite, diarrhea;*

- *Skin rash, reddened or draining eyes, wound drainage; and*

- *Frequency/urgency of urination, malodorous urine.*

Observe for cleaning and disinfecting to determine whether:

- *Equipment in transmission based precaution rooms is either dedicated to that resident and appropriately cleaned or is thoroughly cleaned and disinfected between residents using appropriate agents and procedures;*

- *High touch surfaces in the environment are visibly soiled (i.e., contaminated) or have been cleaned and disinfected;*

- *Small non-disposable equipment such as glucose meters, scissors, and thermometers are cleaned and appropriately disinfected after each use for individual resident care;*

- *Single-use items (e.g., blood glucose lancet, other sharps) are properly disposed of after one use;*

- *Single resident use items (e.g., basins, bed pans) are maintained to be visibly clean for use, and are disposed of after use by a single resident;*

- *Resident dressings and supplies are properly stored to maintain their integrity, and soiled dressings and supplies are appropriately discarded; and*

- *Multiple use items (e.g., shower chairs, bedside scales, resident lifts, commodes, tubs) are properly cleaned/disinfected between each resident use.*

Observe whether hand hygiene and use of gloves (when indicated) is in accordance with current standards. Hand hygiene should occur before and after putting on sterile gloves and after taking off all gloves during all resident care that requires the use of gloves. This includes:

- *Medication administration (e.g., eye drops, sublinguals, and injections);*
- *Dressing changes that require the use of gloves (e.g., anticipated contact with body fluid, excretions, tissue and specimens);*
- *Insertion or removal of a catheter; and*
- *Any invasive procedure.*

Note the availability of gloves and the equipment and products to perform hand hygiene.

2. Interview

During the resident review, interview the resident, family or responsible party to the extent possible to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Interview direct care staff to determine:

- *Whether they are aware of and have reported any signs or symptoms exhibited by the resident that may be associated with an infection;*
- *Whether they are aware of and have been instructed on any special precautions that are applicable to any resident on transmission based precautions;*
- *Whether they are familiar with the indications for washing hands and/or using alcohol based products and understand the basis for the use of gloves and when they are to be removed;*
- *How staff know which residents are covered by transmission-based precautions; and*
- *Whether staff is aware of what specific actions are required for each type of transmission-based precautions.*

3. Record Review

Review the resident's record to determine, for example:

- *Whether the resident's record included an evaluation of the factors which may increase a resident's risk of infection (e.g., indwelling urinary catheters, intravenous catheters, and tracheostomy tubes), and if an infection is present, whether the resident's record reflects the identification of the infection, potential causes and contributing factors; and*

- *Whether the resident's plan of care identifies interventions (device management and isolation precaution measures) to prevent the transmission of infection.*

Review the facility's record of incidents of infection and related corrective actions to help determine whether the facility is identifying, recording, and analyzing infections.

In order to investigate identified infection control concerns, review, as applicable, the facility's:

- *Infection control policies to determine if they are consistent with current professional standards of practice and if the infection control policies are defined by department (e.g., dietary, nursing, laundry);*

- *Documentation of whether and how the infection prevention and control program collects, analyzes, and uses data and implements a program to guide all disciplines to prevent the spread of infections and identify infections in a standardized and systematic way;*

- *Policies regarding handling and processing soiled linens as well as handling, transporting, and storing clean linens;*

- *Applied preventive components of the infection prevention and control program in the care of individual residents;*

- *Policies, procedures, and documentation regarding identifying and prohibiting contact with residents or food by employees with open lesions or communicable diseases and addressing occupational communicable disease exposure and post-exposure follow up;*

- *Employee records to determine if employees receive initial and ongoing employee infection control training regarding critical elements of the infection control plan; and*

- *Documentation related to their review of the appropriateness and effectiveness of antibiotics for residents that are identified as receiving antibiotics.*

4. Interview the Designated Infection Control Representative

If concerns are identified, (e.g., practices are not consistent with accepted principles of infection control or residents are exhibiting symptoms of infections, but have not been assessed or surveillance data are not available or being utilized) interview the facility staff members who are responsible for implementing and overseeing the infection prevention and control program. Investigate as appropriate, for example, whether:

- *The facility identifies where infections are acquired (e.g., nursing home, hospital, or community);*

- *The infection prevention and control program includes any review, in addition to the medication regimen review, of whether antibiotic use in the nursing home is appropriate and effective;*

- *Staff training includes critical areas of infection control such as hand hygiene, areas for improvement from surveillance data, and appropriate use of protective equipment and isolation precautions; how staff are apprised of changes in policies and procedures;*

- *The facility collects, analyzes, and uses data related to infections, to identify and prevent the spread of infections and to adjust its infection prevention and control program,(e.g., policies and procedures) as appropriate;*

- *The program implements processes to identify and address infection control issues and to monitor staff hand hygiene and sterile technique, and the implementation and discontinuation of transmission-based or other isolation precautions and cohorting or separating as applicable;*

- *The facility appropriately implements and discontinues transmission based precaution procedures, and communicates initiation and discontinuation of these transmission-based precaution policies across departments;*

- *The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners) with infections;*

- *The facility has policies and procedures addressing linen handling and how it monitors how linens are stored, transported, processed, to prevent the spread of infection;*

- *The infection prevention and control program identifies and addresses infection control issues, for example whether the facility's infection control practices are consistent with CDC recommendations; and*

- *The facility effectively identifies and prevents employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.*

DETERMINATION OF COMPLIANCE CRITERIA FOR COMPLIANCE

Synopsis of Regulation (F441)

Criteria for Compliance

The facility is in compliance with 42 CFR 483.65 Infection Control, if:

- *The infection prevention and control program demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection, to the extent possible;*

- *The facility demonstrates practices to reduce the spread of infection and control outbreaks through transmission-based precautions (e.g., isolation precautions);*

- *The facility demonstrates practices and processes (e.g., intravenous catheter care, hand hygiene) consistent with infection prevention and prevention of cross-contamination;*

- *The facility demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;*

- *The facility has processes and procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease;*

- *The facility consistently demonstrates appropriate hand hygiene (e.g., hand washing) practices, after each direct resident contact as indicated by professional practice; and*

- *The facility demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.*

If not, cite at Tag F441.

Noncompliance for F441

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F441 may include, but is not limited to, failure to do one or more of the following:

- *Develop an infection prevention and control program;*

- *Utilize infection precautions to minimize the transmission of infection;*

- *Identify and prohibit employees with a communicable disease from direct contact with a resident;*

- *Demonstrate proper hand hygiene;*

- *Properly dispose of soiled linens;*

- *Demonstrate the use of surveillance; or*

- *Adjust facility processes as needed to address a known infection risk.*

Potential Tags for Additional Investigation

During the investigation of F441, the surveyor may have identified concerns with additional outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some related requirements that may be considered when non-compliance at F441 has been identified include the following:

- *42 CFR §483.20(b), F272, Comprehensive Assessments*
    - *If the infection or risks were present at the time of the required comprehensive assessment, determine whether the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's condition and the impact upon the resident's function, mood, and cognition.*
- *42 CFR §483.20(b), F274, Significant Change Assessments*
    - *If there was a significant change infection or risk to the resident's condition, determine whether the facility did a significant change comprehensive assessment within 14 days.*
- *42 CFR §483.20(k)(1)(i), F279, Comprehensive Care Plan*
    - *Determine if the facility developed a care plan consistent with the resident's specific infection status, risks, needs, behaviors, and current standards of practice and included measurable objectives and timetables, and specific interventions/services to prevent the onset and/or transmission of infection.*
- *42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision*
    - *Determine whether staff reassessed the effectiveness of the interventions and review and revised the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident.*
- *42 CFR §483.25(l), F329 Unnecessary Drugs*
    - *Determine if the facility has reviewed with the prescriber the rationale for placing the resident on an antibiotic to which the organism seems to be resistant or when the resident remains on antibiotic therapy without adequate monitoring or appropriate indications, or for an excessive duration.*
- *42 CFR §483.25(l)(2)(n), F334,Influenza and Pneumococcal Immunizations*
    - *Determine if the facility has systems in place to immunize residents against influenza and pneumococcal infections.*
- 42 CFR §483.35(i)(2), F371, Sanitary Conditions
    - *Determine if the facility has implemented processes to prevent infection transmission via food handling, storing and delivery systems.*
- *42 CFR 483.75(f) (F498) Proficiency of Nurse Aides*

- *Determine whether the nurse aides demonstrate the knowledge and skills regarding use of accepted infection control principles, e.g., hand hygiene, transmission barriers, signs and symptoms of infection to report to the nurse, etc.*

V. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

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

The key elements for severity determination for Tag F441 are as follows:

1. ***Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services.*** *Actual or potential harm/negative outcomes for F441 may include but are not limited to facility failure to:*

   - *Properly implement transmission based precautions when indicated resulting in an increase (or potential) of infections or communicable diseases;*
   - *Develop and implement corrective actions despite recording an increase in infections in the facility;*
   - *Recognize and act on an increase or trend in infections within the facility;*
   - *Prohibit employees with symptoms of active communicable infections from continuing to provide resident care or have direct contact with food;*
   - *Properly perform hand hygiene when entering and exiting the room of a resident on special precautions; and*
   - *Recognize and investigate a resident's complaints of rash and pruritis resulting in additional resident's requiring treatment for scabies.*

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

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

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

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

Severity Level 4 Considerations: Immediate jeopardy to resident health or safety

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

- *With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and*

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

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

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

- *The facility failed to follow standard precautions during the performance of routine testing of blood sugars. The facility did not clean and disinfect the glucometers before or after use and did not use new glucometer lancets on residents who required blood sugar monitoring. This practice of not cleaning and disinfecting glucometers between every use and re-using glucometer lancet created an Immediate Jeopardy to resident health by potentially exposing residents to the spread of blood borne infections for multiple residents in the facility who required blood sugar testing.*

- *The facility failed to restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of one or more residents under that staff person's care.*

- *The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses and had to be hospitalized for dehydration.*

  ***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 or the potential for more than minimal harm at Level 2 exists.*

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

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

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

- *The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents acquiring antibiotic-related colitis and significant weight loss.*

- *The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit or section of the facility.*

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

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

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

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s). Examples of avoidable outcomes include, but are not limited to:

- *The facility failed to ensure that their staff demonstrates proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.*
- *The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired from community-acquired infections.*
- *The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify cause, institute measures to correct the problems, or try to correct those problems.*

Severity Level 1: No actual harm with potential for minimal harm

The failure of the facility to provide appropriate care and services for infection control practices, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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[i] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 71. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[ii] *Centers for Disease Control and Prevention (CDC). (2002). Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002; 51 (No.RR-16). pp. 3. Accessed December 10, 2008 from http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf*

[iii] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 71. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[iv] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 70. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[v] *Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). Management of multidrug-resistant organisms in healthcare settings, 2006. Pp. 5. Accessed December 8, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf*

[vi] *American Medical Directors Association (AMDA). (2006). Clinical practice guideline; managing common infections in the assisted living setting. Assisted Living Consult, Jan/Feb 2006: Pp.31*

[vii] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 66. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[viii] *Nicolle, L.E., Strausbaugh, L.J., and Garibaldi, R.A. (1996, Jan.). Infections and antibiotic resistance in nursing homes. Clinical Microbiology Reviews. 9(1): 1-17*

[ix] *Richards, C. (2002). Infections in residents of long-term facilities. J AM Geriatr Soc 2002; 50. Pp.676.*

[x]*Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J., Mody, L., Nicolle, L., and Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. Infect Control Hosp Epidemiology 29(9): Pp.795*

[xi]*Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J., Mody, L., Nicolle, L., and Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. Infect Control Hosp Epidemiology 29(9): Pp.803.*

[xii] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 78. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xiii]*Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xiv]*Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 79. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xv] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xvi]*Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xvii] *Centers for Disease Control and Prevention (CDC). (2008, March). Injection Safety FAQs for Providers. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/injectionSafetyFAQs.html#Q11*

[xviii] *Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J., Mody, L., Nicolle, L., and Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. Infect Control Hosp Epidemiology 29(9): 785-814.*

[xix] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 48. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xx] *Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xxi] *Kim, K.H., Fekety, R., Batts, D.H.,Brown, D., Cudmore, M., Silva, J. Jr., and Waters, D. (1981, Jan. 1). Isolation of Clostridium Difficile from the environment and contacts of residents with antibiotic-associated colitis. Journal of Infectious Disease. 143:1. Pp.42-50.*

[xxii] *Centers for Disease Control and Prevention (CDC). (2008, July 8). Hepatitis B FAQs for healthcare professionals. Accessed December 16, 2008 from http://www.cdc.gov/print.do?url=http%3A//www.cdc.gov/hepatitis/HBV/HBVfaq.htm%23overview*

[xxiii] *Centers for Disease Control and Prevention (CDC). (2007, February 15). Preventing seasonal flu. Accessed December 16, 2008 from http://www.cdc.gov/flu/about/qa/preventing.htm*

[xxiv] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp.61. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xxv] *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration (FDA). (2005). Food Code. Pp. 43.*

[xxvi] *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration (FDA). (2005). Food Code. Pp.44*

[xxvii] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June).2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Accessed December10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xxviii] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xxix] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 53. Accessed December10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xxx] *Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geinan, J.M. (1981, Sep.). Infectivity of respiratory syncytial virus by various routes of inoculation. Infection and Immunity. 33(3). Pp.782.*

[xxxi] *Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Infection Control Practices Advisory Committee. (2007 June). 2007 Guideline for Isolation Precautions: Preventing transmission of infectious agents in healthcare settings. Pp. 17. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf*

[xxxii] *Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Pp.139. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xxxiii] *Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Pp.139. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xxxiv] *Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Pp. 139. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xxxv] *Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Pp. 140. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf*

[xxxvi] *American Medical Directors Association (AMDA). (2006). Clinical practice guideline; managing common infections in the assisted living setting. Assisted Living Consult, Jan/Feb 2006: Pp.31*

[xxxvii] *American Medical Directors Association (AMDA). (2001). Critical Issues in Infection Control, Focusing on VRE and MRSA in LTC Setting.*

[xxxviii] *Williams, R.E.O. (1963). Healthy carriage of Staphylococcus aureus: its prevalence and importance. Bacterial Rev. 1963; 27:56-71*

[xxxix] *Mayfield, J.L., Leet, T., Miller, J., and Mundy, L.M. (2000, Oct. 25). Environmental control to reduce transmission of Clostridium Difficile. Clinical Infectious Disease. 2000;31. Pp.998*

[xl] *Morbidity and Mortality Weekly Report. (2002, August). Guidelines for the Prevention of Intravascular Catheter-Related Infections Vol. 51, RR-10. Centers for Disease Control and Prevention (CDC).*

Slide 1

§483.65 Infection Control (F441)

Surveyor Training of Trainers:

Interpretive Guidance

Investigative Protocol

Instructor Notes:

Objectives:

Identify compliance with the regulation as it relates to infection prevention

Appropriately identify the severity of noncompliance

Slide 2

Tags Collapsed

- **With regard to the revised guidance F441 Infection Control, there have been significant changes. Namely, F Tags 441, 442, 443, 444, and 445 have been collapsed into this single guidance at F441. However, the regulatory language has remained the same.**

Instructor Note:

The revisions to F441 were made to provide definition, education, explanation, and examples for the surveyors to reference

Slide 3

Federal Regulatory Language

§483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

Instructor Notes:

This is the regulatory language for Infection Control at F441. Please note that this regulatory language has not changed.

Understanding the regulation is key to facilitating the accurate documentation of the findings.

Slide 4

§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

1) Investigates, controls, and prevents infections in the facility;

Slide 5

§483.65(a) Infection Control Program

2) Decides what procedures, such as isolation, should be applied to an individual resident; and

Slide 6

§483.65(a) Infection Control Program

3) Maintains a record of incidents and corrective actions related to infections.

Slide 7

§483.65(b) Preventing Spread of Infection

1) **When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.**

Slide 8

§483.65(b) Preventing Spread of Infection

2) **The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.**

Instructor Notes:

Stress the importance of the second part of this statement, that the direct contact must be a means by which the disease will be transmitted. Ask surveyors for examples of diseases that are and are not transmitted in this manner.

Slide 9

§483.65(b) Preventing Spread of Infection

3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

Slide 10

§483.65(c) Linens

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

Slide 11

Intent

The intent of this regulation is to assure that the facility, develops, implements and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility.

Instructor Notes:

The facility is expected to take action to help the resident attain or maintain his or her highest practicable level of physical, mental, and psycho-social well-being, including managing the resident's infection status.

Slide 12

§483.65 Infection Control
Interpretive Guidelines Background

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals.

Infections occur an average of 2 to 4 times per year for each nursing home resident.

Instructor Notes:

Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of $673 million to $2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

Slide 13

Endemic Infections in Nursing Home Residents

Most Frequently Occurring:

- **Urinary tract**
- **Respiratory**
- **Skin and Soft Tissue**

Other Commonly Occurring:

- **Conjunctivitis**
- **Gastroenteritis**
- **Influenza**

Instructor Notes:

There are many examples of respiratory infections, such as pneumonia and bronchitis. Ask surveyors for other examples.

Skin and soft tissue infections include pressure ulcers, a frequent type of infection in nursing home residents. There is a separate Tag that specifically addresses these infections. Discuss this issue.

Slide 14

Critical Aspects of Infection Prevention and Control Programs

- **Recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay**

- **Following recognized infection control practices while providing care**

Instructor Notes:

Bullet 1: Note that infection prevention and control is a continual process that must continue through the duration of a resident's stay at a nursing home. Older adults often have coexisting diseases (e.g. COPD, arthritis) and/or atypical or non-specific signs of infection (e.g. altered mental status, impaired fever response).

Bullet 2: Examples of recognized infection control practices include hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents.

Slide 15

Considerations

It can be difficult to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

Instructor Notes:

It is important to recognize the potential negative impact that a resident may experience as a result of the implementation of special precautions.

While this Interpretive Guidance will offer some general and specific information related to infection prevention and control, actual practices should reflect current CDC guidelines and must be updated as those guidelines are revised.

It is important that all infection prevention and control practices reflect current CDC guidelines.

Following current CDC guidelines will help ensure that infection control practices are implemented in a manner that is consistent and based upon the latest scientific evidence, therefore standardizing the care and treatment of the residents.

Slide 16

Components of an Infection Prevention and Control Program

- **Program Development and Oversight**
- **Policies and Procedures**

- **Infection Preventionist**

Surveillance

- **Documentation**
- **Monitoring**
- **Data Analysis**
- **Communicable Disease Reporting**
- **Education**
- **Antibiotic Review**

Instructor Notes:

These are the components of an effective infection prevention and control program. We will discuss each of these aspects in more detail in the slides that follow.

Slide 17

Program Development & Oversight: Core Focus

- **Establishing goals and priorities**
- **Monitoring implementation of the program**
- **Responding to errors, problems, or other identified issues**

Instructor Notes:

Program development and oversight emphasize the prevention and management of infections. Goals and priorities must be established in order for the program to be assessed in terms of effectiveness and utility.

The infection control and prevention program provides the foundation for clinicians and staff to help each resident attain and/or maintain his or her highest practicable level of well-being, including preventing or managing infections, to the extent possible.

Throughout this guidance, the infection prevention and control program has been based upon an interdisciplinary approach. This interdisciplinary team's infection control practices are monitored as part of the program oversight.

Slide 18

Program Development and Oversight: Additional Activities

- **Identifying roles and responsibilities during routine implementation as well as unusual occurrences or threats of infection**
- **Defining and managing resident health initiatives**
- **Managing food safety**
- **Providing a nursing home liaison to work with local and state health agencies**

Instructor Notes:

These are just some examples of the many different activities that may be conducted as part of the infection prevention and control program development and oversight.

Bullet 1: Unusual occurrences may include an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack.

Bullet 2: Resident health initiatives might include immunization programs or health screenings. F334 focuses on influenza and pneumococcal vaccination. Encourage surveyor discussion of various types of resident health initiatives and how they might relate to the infection prevention and control program.

Bullet 3: Food safety is addressed specifically in a separate Tag. However, it is mentioned here as it can be a source of infection (e.g. salmonella). Items to consider with regard to food safety include employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.

Bullet 4: The nursing home liaison may work with the health agencies on a routine basis as well as during times of outbreaks, epidemics, natural emergencies, or other emergencies.

Slide 19

Program Development and Oversight: Personnel

Personnel are identified as being responsible for overall program oversight.

May include the collaboration of the:

- **Administrator**
- **Medical Director (or a designee)**
- **Director of Nursing**
- **Other staff as appropriate**

Instructor Notes:

This team will:

- Define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program
- Communicate the findings from collecting and analyzing data to the facility's staff and management
- Direct changes in practice based on identified trends, government infection control advisories, and other factors.

Slide 20

Policies and Procedures

- **Written policies establish the program's expectations and parameters**
- **Procedures guide the implementation of the policies and performance of specific tasks**

These serve as the foundation to the program and should undergo periodic review and revision to conform to current standards of practice or to address specific facility concerns

Instructor Notes:

- Policies may: specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease

- Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

Slide 21

Infection Preventionist (IP)

Serves as the coordinator of the program and responsibilities may include:

- **Education and training;**
- **Collecting, analyzing, and providing infection data and trends to nursing staff and healthcare practitioners; and**
- **Consulting on infection risk assessment, prevention, and control strategies.**

Instructor Notes:

Infection Preventionist or the designee will most often have primary training in either nursing, medical technology, microbiology, or epidemiology and may possess additional training in infection control. However, there are no regulatory requirements regarding this position and therefore a facility may choose not designate a specific IP or may designate an individual with a background not mentioned here.

Responsibilities may also include: implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control.

Slide 22

Surveillance

- **Essential Elements**
- **Two Types**
  - **Process**
  - **Outcome**

Instructor Notes:

As a reminder, surveillance has been defined previously as the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.

Essential elements of surveillance include:

- The use of standardized definitions and listings of the symptoms of infections;
- The use of surveillance tools such as infection surveys and data collection templates;
- Conducting walking rounds throughout the facility;
- The identification of segments of the resident populations at risk for infection;
- The identification of the processes or outcomes selected for surveillance;
- The statistical analysis of data that can uncover an outbreak; and
- The feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Slide 23

Process Surveillance

Process surveillance reviews practices directly related to resident care in order to identify whether the practices are compliant with established prevention, control and policies based on recognized guidelines.

Instructor Notes:

Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene, and the use and disposal of gloves.

Process surveillance determines, for example, whether the facility:

- Minimizes exposure to a potential source of infection;
- Uses appropriate hand hygiene prior to, and after, all procedures;
- Ensures that appropriate sterile techniques are followed.; for example, that staff:

- Use sterile gloves, fluids and materials, when indicated; depending on the site and the procedure;
- Avoid contaminating sterile procedures; and
- Ensure that contaminated/non-sterile items are not placed in a sterile field.
- Uses Personal Protective Equipment (PPE) when indicated;
- Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and
- Uses single-use medication vials and other single use items appropriately (proper disposal of after every single use)

Slide 24

Outcome Surveillance

Outcome surveillance is designed to identifies and reports evidence of an infectious disease. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections.

Instructor Notes:

The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends.

Other sources of relevant data may include:

- antibiotic orders
- laboratory antibiograms (antibiotic susceptibility profiles)
- medication regimen review report and
- medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.

Regulatory language mandates that the facility must "maintain records of incidents and corrective actions related to infections." Therefore, the facility's program must choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the

facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.

Slide 25

Documentation

- **Various approaches to gathering, documenting and listing surveillance data**
  - **Infection control reports describe the types of infections and are used to identify trends and patterns**

It is up to the program to define how often and by what means surveillance data will be collected.

Instructor Notes:

Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

The facility might create its own forms, purchases preprinted forms, or use automated systems.

Slide 26

Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance.

Instructor Notes:

The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents shall be monitored for current infections and infection risks.

Slide 27

Data Analysis

- **Comparing past and present surveillance data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues.**
    - **Processes and/or practices can be changed to enhance infection prevention and minimize the potential for transmission of infections.**

Instructor Notes:

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home.

In order for data analysis to be useful, it is important that surveillance reports be shared with appropriate individuals including, but not limited to, the clinical professional staff.

In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

Slide 28

Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with state and local health department requirements for reporting communicable diseases.

Instructor Notes:

State and local health departments have varying requirements for reporting communicable diseases. Engage the surveyors in a brief discussion of some examples of diseases that might require reporting.

Slide 29

Education

- **Both initial and ongoing infection control education help staff understand and comply with infection control practices.**

- **In addition to general infection control principles, some infection control training is discipline and task-specific.**

Instructor Notes:

Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.

Essential topics of an infection control training include, but are not limited to:

- routes of disease transmission
- hand hygiene
- sanitation procedures
- MDROs
- transmission-based precaution techniques and
- federally required OSHA education.

Examples of discipline and task specific training include:

- urinary catheter insertion
- Suctioning
- IV Care and
- blood glucose monitoring.

The facility should utilize follow-up competency evaluations to identify staff compliance.

Encourage the surveyors to provide additional examples of general and task/discipline specific training topics. Emphasize that this training may be conducted facility-wide, by department, or on an individualized basis. It may also include training that occurs off-site.

Slide 30

Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program.

Instructor Notes:

It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications.

The consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the Director of Nursing and the attending physician.

See F329 regarding use of a medication without adequate indication for use and F428 regarding medication regimen review.

Slide 31

Preventing the Spread of Infection

- **Individual and institutional factors contribute to the increased frequency and severity of infections in nursing homes**
- **Modes of transmission include:**
    - **Contact**
    - **Droplet**
    - **Airborne**

Instructor Notes:

In order to prevent the spread of infection, it is necessary to understand the factors and modes of transmissions.

While there are other modes of transmission, the three listed here (contact, droplet, and airborne) are further examined in this Guidance for their applicability to nursing homes.

Solicit examples of each mode of transmission from the surveyors.

Slide 32

Individual Factors:

- **Medications**
- **Limited physiologic reserve**
- **Compromised host defenses**
- **Impaired responses**
- **Coexisting chronic diseases**
- **Complications from invasive procedures**
- **Increased frequency of therapeutic toxicity**

Instructor Notes:

These are examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents. Many of these factors affect older adults in general.

- Medications affecting resistance to infection; e.g., corticosteroids and chemotherapy;
- Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);
- Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);
- Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);
- Complications from invasive diagnostic procedures such as skin or bloodstream infections;
- Impaired responses to infection (e.g., cell mediated responses); and
- Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).

Slide 33

Institutional Factors:

- **Pathogen exposure in shared communal living space (e.g. handrails and equipment);**
- **Common air circulation;**

- **Direct/indirect contact with healthcare personnel/visitors/other residents;**
- **Direct/indirect contact with equipment used to provide care; and**
- **Transfer of residents to and from hospitals or other settings.**

Instructor Notes:

After reading the list the surveyors, ask for their input as to how or why these factors may facilitate transmission of infections among nursing home residents.

It is also important to note that residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- Improper hand hygiene
- Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents)
- Improper food handling

Slide 34

Direct Transmission
(Person to Person)

Direct transmission occurs when microorganisms are transferred from one infected/colonized person to another with a contaminated intermediate object or person.

Contaminated hands of healthcare personnel are often implicated in direct contact transmission.

Instructor Notes:

Some examples of agents that can be transmitted directly from person to person include MRSA, VRE, and Influenza.

Slide 35

Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object or person. Examples include:

- **Resident care devices**
- **Clothing, including Proper Protective Equipment (PPE)**
- **Toilets and bedpans**

Instructor Notes:

Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents.

Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and Clostridium difficile).

Indirect contact through toilets and bedpans. Examples of illnesses spread via a fecal-oral route include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.

Slide 36

Indirect Transmission (cont'd)

To reduce or prevent infections transmitted via indirect contact, resident equipment, medical devices, and the environment must be decontaminated.

- **Single-use disposable devices may also be used.**

Instructor Notes:

The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices. This will be discussed further in the following slides.

Slide 37

Indirect Transmission (cont'd)

3 Risk levels associated with instruments commonly used in Nursing Homes

1. **Critical**
2. **Semi-Critical**

3. **Non-Critical**

Instructor Notes:

1. Critical items (e.g. needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures.
2. Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA approved chemo sterilizer agent, or they may be sterilized.
3. Noncritical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Devices labeled by the manufacturer for single use are never to be reused, even if they are reprocessed.

Slide 38

Prevention and Control of Transmission of Infection: Standard Precautions

- **based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents**
- **intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent**

Instructor Notes:

Implementation of Standard Precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures are used in each resident interaction.

Slide 39

Standard Precautions (cont'd)

Examples of standard precautions include:

- **hand hygiene**
- **safe injection practices**
- **the proper use of personal protective equipment**
- **care of the environment, textiles and laundry**
- **resident placement**
- **appropriate waste disposal and management**

Instructor Notes:

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g. sharps containers, biohazard bags, etc.), and the environment is cleansed using germicidal agents to reduce the risk of transmission of infection.

Slide 40

Personal Protective Equipment (PPE)

- **PPE includes items such as gloves, gowns, eye protection, and masks**
- **These items are used as barrier to any body fluids or other potentially infected materials**

Instructor Notes:

For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections.

Standard Precautions are intended to protect health care personnel as well as residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care, or vice versa.

Any equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g. wear gloves for handling soiled equipment, and properly clean and disinfect or sterilize reusable equipment before use on another resident).

Slide 41

Hand Hygiene

Primary means of preventing the transmission of infection

Requires proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods

ABHR may be utilized in situations where hand washing with soap and water is not specifically required

Instructor Notes:

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections.

Slide 42

Hand Hygiene (cont.)

1. **Wet hands with clean, running warm water**
2. **Apply the amount of product recommended by the manufacturer to the hands**
3. **Rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers**
4. **Rinse hands with water and dry thoroughly with a disposable towel or heat/air dryer**
5. **Turn off the faucet on the sink with a disposable paper towel, if available**

Slide 43

Other Staff-Related Preventive Measures

- **Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease.**
- **Personal hygiene must be maintained in a manner so as to minimize the potential for harboring and/or transmitting infectious organisms.**

Instructor Notes:

- Bullet 1: This is mandated by the regulatory language. Therefore, it is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.

- Bullet 2: It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and remove hand jewelry when handling food. These recommendations apply even when the use of gloves is employed. This issue is further addressed in the F371 (Sanitary Conditions) Guidance.

Slide 44

Transmission-Based Precautions
(formerly Isolation Precautions)

- **Used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission.**
- **It is appropriate to individualize decisions regarding resident placement based on a number of factors.**

Instructor Notes:

The facility may balance infection risks with:

- the need for more than one occupant in a room
- the presence of risk factors that increase the likelihood of transmission and
- the potential for adverse psychological impact on the infected or colonized resident

In order for transmission-based precautions to be an effective means of infection control and prevention, it is essential both to communicate Transmission-Based Precautions to all healthcare personnel, and for personnel to comply with requirements.

Pertinent signage, verbal reporting of findings, and observations for compliance all can enhance compliance and help minimize the transmission of infections within the facility.

Slide 45

Transmission-Based Precautions (cont'd)

Transmission-Based Precautions shall be maintained for only as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others.

Instructor Notes:

- Maintaining isolation longer than necessary may adversely affect psychosocial sell-being. The facility should document in the resident's medical record the rationale for the selected Transmission-based Precautions.
- The category of Transmission-based Precaution determines the type of personal protective equipment to be used. When transmission-based precautions are in place, the appropriate personal protective equipment should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of Transmission-based Precaution employed.
- Standard approaches are defined by the CDC for Airborne, Contact, and Droplet Precautions.

Slide 46

Airborne Precautions

- **Intended to prevent the transmission of organisms that remain infectious when suspended in the air.**
  - **E.g. varicella zoster [shingles] and M. tuberculosis**
- **Personnel caring for residents on Airborne Precautions wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.**

Instructor Notes:

- Bullet 1: Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity.
- Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed.

- It is important for the facility to have a plan in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer.
- Bullet 2: Depending on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.

Slide 47

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact.

Slide 48

Droplet Precautions

Respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient.

Instructor Notes:

Respiratory droplets are generated when an infected person coughs, sneezes, or talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth. Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.

Slide 49

Airborne precautions require mask or respirator, gloves and private room or cohorting and room sharing with limited risk factors. Private AIIR room with active TB

Contact precautions require gown and gloves, and private room or cohorting and room sharing with limited risk factors.

Droplet precautions require mask/facila protection, gloves and private room or cohorting and room sharing with limited risk factors. 3-10 feet distance* for transmission

All Transmission-based Precautions require appropriate hand hygiene practices

Instructor Notes:

*The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet

It is important that facility staff clearly identify the type of precautions and the appropriate personal protective equipment to be used in the care of the resident. Personal protective equipment shall be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

Slide 50

Implementation of Transmission-Based Precautions

Since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, Transmission-Based Precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.

Instructor Notes:

It is not always possible to identify prospectively residents needing Transmission-Based Precautions. The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation.

Use of appropriate Transmission-Based Precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.

Slide 51

Safe Water Precautions

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water.

Instructor Notes:

The FDA nationally recognized standard for safe drinking water is <500 CFU/mL per heterotrophic plate count.

Slide 52

Handling Linens to Prevent and Control Infection Transmission

If the facility handles all used linen as potentially contaminated (i.e. using Standard Precautions), no additional separating or special labeling of the linen is recommended

If Standard Precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is needed.

Instructor Notes:

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission.

No special precautions (i.e. double bagging) or categorizing is recommended for linen originating in isolation rooms. Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances.

It is important that laundry areas have hand washing facilities and products, as well as appropriate PPE (i.e., gloves and gowns) available for workers to wear while sorting linens.

Slide 53

Handling Linens (cont'd)

If linen is sent off to a professional laundry facility, the nursing home facility obtains an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport.

Slide 54

Handling Linens (cont'd)

An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160ºF (71ºC) for 25 minutes. Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles

Instructor Notes:

Laundry equipment shall be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system. If laundry chutes are used, they are properly designed, maintained, and used so as to minimize dispersion of aerosols from contaminated laundry (e.g. no loose items in the chute and bags are closed before tossing into the chute).

Damp linen is not left in machines overnight.

Slide 55

Handling Linens (cont'd)

Standard mattresses and pillows can become contaminated with body substances during patient care

- **Clean and disinfect moisture-resistant mattress covers between patients with an EPA approved germicidal detergent. All fabric mattress covers are to be laundered between patients.**
- **Launder pillow covers and washable pillows in hot water cycle between residents or when they become contaminated with body substances.**

Instructor Notes:

A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. Mattress covers are recommended to be replaced when torn or visibly stained.

Discarding mattresses if fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.

Slide 56

Recognizing and Containing Outbreaks

An outbreak is typically one of the following:

- **One case of an infection that is highly communicable.**
- **Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation.**
- **Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.**

Slide 57

Recognizing and Containing Outbreaks (cont'd)

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it.

- **State health departments offer guidance and regulations regarding responding to and reporting outbreaks.**
- **Plans for containing outbreaks usually include efforts to prevent further transmission of the infection**

Instructor Notes:

Bullet 2: This information is often received in advance of an outbreak and included in the infection prevention and control program.

Bullet 3: The facility should consider the needs of the residents and staff when developing plans for containing outbreaks.

Slide 58

Prevention of the Spread of Illness Related to Multidrug Resistant Organisms (MDROs)

- **Common MDROs include MRSA, VRE, and Clostridium Difficile**
- **Transmission-based precautions are employed for all MDROs**
- **Aggressive infection control measures and strict compliance can help minimize transmission of MDROs**

Instructor Notes:

Methicillin-resistant staphylococcus aureus (MRSA), vancomycin-resistant enterococcus (VRE), and clostridium difficile will be discussed in detail in the slides that follow.

Slide 59

MRSA

- **Staphylococcus is a common cause of infections**
- **Common sites of colonization include the rectum, perineum, skin and nares**
- **Colonization may precede or endure beyond an acute infection.**

- **MRSA is transmitted person-to-person (most common), on inanimate objects and through the air**

Instructor Notes:

MRSA infection is commonly treated with Vancomycin, which in turn can lead to increased Enterococcus antibiotic resistance.

These points illustrate why antibiotic review and monitoring of residents are important components of an effective infection prevention and control program.

Slide 60

VRE

- **Enterococcus is an organism that normally occurs in the colorectal tract.**
- **VRE is an infection with enterococcus organisms that have developed resistance to the antibiotic Vancomycin**
- **Preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE**

Instructor Notes:

VRE infections have been associated with prior antibiotic use.

This point illustrates why antibiotic review and monitoring of residents are important components of an effective infection prevention and control program.

Slide 61

Clostridium Difficile (C. difficile)

- **C. difficile is a bacterial species of the genus Clostridium, which are gram-positive, anaerobic, spore-forming rods (bacillus).**
- **When antibiotic use eradicates normal intestinal flora, the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever.**

Instructor Notes:

Reference CDC guidelines.

Slide 62

Clostridium Difficile (cont'd)

More severe cases can lead to additional complications such as intestinal damage and severe fluid loss.

If a resident has diarrhea due to C. difficile, large numbers of C. difficile organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Instructor Notes:

Treatment options include stopping antibiotics and starting specific anticlostridial antibiotics, e.g. metronidazole or oral Vancomycin.

Reference current CDC guidelines

Slide 63

Clostridium Difficile (cont'd)

- **Contact Precautions are instituted for residents with symptomatic C. difficile infection**
  - **Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents**
- **C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to six months**

Instructor Notes:

Thorough hand washing with soap and water after caring for the resident can also reduce the risk of cross-transmission.

Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism. Equipment may need to be cleaned with a 1:10 dilution of sodium hypochlorite (bleach). This is one part water to nine parts sodium hypochlorite. Once mixed, the solution is effective for 24 hours.

Reference current CDC guidelines.

Slide 64

Preventing Infections Related to the Use of Specific Devices

- **Intravascular catheters**
  - **used widely to provide vascular access**
  - **increasingly seen in nursing homes**
  - **may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis**

- **Central venous catheters (CVCs) have also been associated with infectious complications.**

Instructor Notes:

Other catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection.

Slide 65

Preventing Infections Related to the Use of Specific Devices (cont'd)

- **Limit access to central venous catheters for only the primary purpose**

- **Consistently use appropriate infection control measures**

  - **surveillance**

  - **observation of insertion sites**

Instructor Notes:

Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as PICC lines, midlines, and peripheral access catheters.

Slide 66

Preventing Infections Related to the Use of Specific Devices (cont'd)

Consistently use appropriate infection control measures

- **routine dressing changes**
- **use of appropriate PPE and hand hygiene**
- **review of resident for clinical evidence of infection**

Slide 67

Investigative Protocol
Objectives determine if

- **The facility has an Infection Prevention and Control Program that prevents, investigates and controls infections in the facility**
- **The facility has a program that collects and analyzes data regarding infections acquired in the facility**
- **Staff practices are consistent with current infection control principles**
- **staff with communicable diseases are prohibited from direct contact with resident**

Instructor Notes:

The objectives of this investigative protocol are to focus the investigation. Surveyors use the protocol to determine whether the facility has a Infection and Prevention Control Program in place and if the facility's program collects and analyzes its data. The protocol helps the surveyor investigate the facility's overall Infection Prevention and Control Program.

Policy and procedures manuals, training documents and monitoring tools may be reviewed during this investigation to assist in determining the facility systems. However it is important to remember that the facility's written policy alone does not confirm compliance with Federal regulatory requirements.

Surveyors, use this protocol to investigate compliance at F441 for every initial and standard survey. In addition, use this protocol on revisit or abbreviated surveys (compliant investigations) as needed.

Slide 68

Procedures

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

Instructor Notes: It is helpful to review this protocol prior to beginning the survey.

- Review the facility's records of incidents of infection and corrective actions, as indicated, review the facility's infection control policies, procedures, documentation of staff training and, as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.
- Throughout the survey, the surveyors should determine if:
- The facility identifies where infections are acquired;
- Staff training includes critical areas of infection control;
- The program implements processes to identify and address infection control issues;
- Factors are used to help the facility appropriately determine when to implement and terminate transmission based precaution procedures;
- The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners with infections;
- The facility has policies and procedures monitoring how linens are stored, transported, and processed;
- The Infection and Prevention Control program identifies and addresses infection control issues; and
- The facility effectively identifies and prevents employees with a communicable disease from direct contact with residents.

Slide 69

Observe Staff

- **Observe various disciplines (nursing, dietary and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures.**

Instructor Notes:

Ask surveyors, what are some examples of what you are looking for during the survey of how linens are handled, transported and stored.

- **Observe when linens are handled, processed, transported and stored**

- **Observe if staff exhibit overt signs of illness or communicable disease that have potential to transmit**
- **Observe if staff and visitors adhere to appropriate precautions**
- **Observe if staff use appropriate precautions if resident are on special precautions**
- **Observe if staff involved in the care and management of residents with special needs (e.g. urinary catheters, wound care, respiratory treatments)**

Slide 70

Observe Residents for:

- **Signs and symptoms of potential infections such as**

  Coughing and/or congestion

  Vomiting or loss of appetite

  Skin rash, reddened or draining eyes

Slide 71

Observe Cleaning and Disinfecting to determine:

- **If equipment in Transmission Based Precaution rooms are appropriately cleaned**
- **If high touch surfaces in the environment are visibly soiled**
- **If small non-disposable equipment are cleaned**

Instructor Notes:

Observe various disciplines (nursing, dietary and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures.

Slide 72

Observe Staff practice to determine:

- **How single-use items are properly disposed of;**
- **How single resident use items are maintained**

- **How resident dressings and supplies are properly stored**
- **If multiple use items are properly cleaned/disinfected between each resident**

Slide 73

Observe Hand Hygiene and use of gloves during:

- **Resident care that requires use of gloves;**
- **Medication administration;**
- **Dressing changes and all resident care that requires use of gloves.**
- **Assisting Residents with Meals.**

Instructor Notes:

Note the availability of gloves and the equipment and products to perform hand hygiene.

Slide 74

Interview

During the resident review, interview the resident, family or responsible party, to the extent possible, to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Instructor Notes:

The interview questions may be asked while the observations are being conducted or separate from the observation. In either case, the surveyors should be sure to document responses accurately to include the name and title of the staff person interviewed. In addition to interviewing the staff involved in the residents care, interviews should also include other facility personnel.

During the course of the survey, also interview direct care staff who perform the tasks about the infection control procedures they follow to care for residents.

Slide 75

Record Review

Review facility documents and interview staff to establish if the facility has processes and practices to promote infection control and prevention the spread of infectious diseases.

Instructor Notes:

Record review is an important part of the investigative process. The necessary supporting data may be:

- Resident records
- Facility Record of Incidents as related to infection control
- Infection Control policies, surveillance documentation
- Employee records
- Documentation related to facility's review of antibiotics

As part of the investigative protocol, obtain the records and interviews to monitor the facility's practice in the procurement, storage, preparation, distribution and service of linen to residents. Conduct the documentation review and staff interviews to identify and analyze any concerns or facility practices that may put residents at risk of infectious diseases.

Ask surveyors to discuss additional information sources that would be helpful to review (e.g., training records, competency testing, equipment repair records, and infection control records regarding surveillance of infectious diseases and outbreaks).

If survey concerns are identified:

Interview facility staff who are responsible for implementing and overseeing the Infection Prevention and Control Program.

Slide 76

Determination of Compliance 483.65 Infection Control

Did the facility:

- **Demonstrate practices to prevent the spread of infections ?**
- **Demonstrate practices to control outbreaks?**

Instructor Notes:

Compliance with the Infection Control regulation occurs when a facility has met both aspects in the prevention of spread of infections and the implementing practices to control outbreaks. The next two slides relate to this discussion.

Slide 77

Criteria for Compliance with F441

The facility is in compliance if staff:

- **Demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection;**
- **Demonstrates practices and processes consistent with infection prevention and prevention of cross-contamination;**

Slide 78

Criteria for Compliance with F441 (cont'd)

The facility is in compliance if staff:

- **Demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;**
- **Uses procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents;**

Instructor's Note:

Compliance at F441 is based in part on the facility's ability to be proactive and act appropriately to infection control issues.

Slide 79

Criteria for Compliance with F441

The facility is in compliance if staff:

- **Demonstrates appropriate hand hygiene practices, after each direct resident contact; and**
- **Demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.**

Instructor's Note:

Discuss with the surveyors the criteria for determining Compliance and Noncompliance with this regulatory requirement.

Slide 80

Noncompliance with F441

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

- **Develop an Infection Control and Prevention Program in accordance with the standards summarized in this guidance**

Instructor Notes:

A clear understanding of the facility's noncompliance with requirements (i.e., deficient practices) is essential to determine how the deficient practice(s) relates to any actual harm or potential for harm to the resident. Noncompliance must be established before determining severity.

Slide 81

Noncompliance with F441 (cont'd)

Failure to:

- **Utilize infection precautions to minimize the transmission of infection;**
- **Identify and prohibit employees with a communicable disease from direct contact with a resident;**
- **Demonstrate proper hand hygiene;**
- **Properly dispose of soiled linens;**

Slide 82

Noncompliance with F441 (cont'd)

Failure to:

- **Demonstrate the use of surveillance; and**
- **Adjust facility processes as needed to address a known infection risk.**

Instructor Notes:

It is important that the facility monitor and track current infection control and prevention activities. The facility needs to act appropriately and institute processes to address infection risks to residents.

Observed facility practices (e.g., interviews), that reveal lack of knowledge among staff members about these processes, and inadequate facility documentation of compliant practices can confirm deficient practices in this area.

Slide 83

DEFICIENCY CATEGORIZATION
(Part IV, Appendix P) Severity Determination
Key Components

Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,

Degree of harm (actual or potential) related to noncompliance, and

Immediacy of correction required.

Instructor Notes:

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.

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Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F441 may include:

- **Onset of infections in the facility**
- **Spread of infection within the facility**

- **An infection outbreak in the facility**

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Determining Degree of Harm

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

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

Instructor Notes:

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 F441. 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).

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Level 4 Immediate Jeopardy

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

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Level 4 Immediate Jeopardy (cont'd)

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

Instructor Notes:

Discuss examples of immediate jeopardy that you have seen in your experiences?

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Level 4 Examples

The facility failed to clean the spring-loaded lancet devices before or after use and reused lancet devices on residents who required blood sugar monitoring. This practice of re-using lancet devices created an Immediate Jeopardy to resident health by potentially exposing residents to the spread of blood borne infections for multiple residents in the facility who required blood sugar testing.

Instructor Notes: level 4 examples cont.

- The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses and had to be hospitalized for dehydration.
- The facility failed to restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of several residents under that staff person's care.

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Severity Level 3 Actual Harm that is *not* Immediate Jeopardy

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

Instructor Note:

What is harm that is not immediate jeopardy?

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Level 3 Example

The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents who get antibiotic-related colitis and significant weight loss.

Instructor Notes: Additional examples of level 3:

- The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit.

- The facility failed to ensure courses of antibiotic therapy for residents with urinary tract infections were effective resulting in two residents developing Urosepsis and requiring hospitalization for intravenous antibiotic therapy.

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Level 2 No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- **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.**

Instructor Notes:

Next slide - Level 2 examples

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Level 2 Example

The facility failed to ensure that their staff demonstrate proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.

Instructor Notes:

Other examples of level 2:

- The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired from community-acquired infections.
- The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify cause, institute measures to correct the problems.

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Level 1 No Actual Harm with Potential for Minimal Harm

The failure of the facility to develop, implement and maintain an infection prevention and control program to prevent, recognize, and control the onset and spread of infections places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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Questions?