



10 Critical Requirements of a Successful Infection Prevention Program

Goals and Objectives

Goal

- To familiarize Ambulatory Surgery Leadership with the Revised CMS, and accreditation, Infection Prevention/Control Program (IP) Requirements

Objectives

- Identify two resources for required nationally recognized infection prevention/control guidelines
- The participant will be able to identify the essential documents and activities for demonstrating compliance with CMS and Accreditation Infection Prevention (IP) standards.

How did we get here?

- **CDC estimates currently there are approximately 2,000,000 healthcare associated infections (HAIs) and 100,000 related deaths each year**
- **Many pathogens responsible for these events were transmitted from environmental surfaces and unsafe provider practices**
- **As healthcare providers, we are responsible for many of these infections**

In the News

- **In a Nebraska ASC, a nurse exposed hundreds of patients to Hepatitis C when she accessed a 500ml saline bag with a Hep C contaminated syringe, continuing to fill 10cc syringes from this bag for hundreds of patients**
- **Exposures to HIV and hepatitis in ASCs:**
 - Las Vegas ASC — 63,000 endoscopy patients
 - Michigan — 20,000 dermatology patients
 - New York — 14,000 cardiology patients
 - North Carolina — 1,200 cardiology patients

That we know of

- **99 cancer patients treated at the Nebraska ASC have become infected with Hep C alone**
- **35 outbreaks of viral hepatitis in non-hospital healthcare settings over the last decade (Garman, 2009)**

Why?

- Educated, licensed, professional healthcare providers, charged with protecting the life and health of the patients entrusted to them, failed to change syringes between patient injections, exposing thousands to diseases and causing at least two deaths (Battaglio, 2009)

The toll is staggering

- Lives lost
- Healthy patients now with life-long diseases
- In addition to human suffering, it is estimated
HAIs incur \$28 to \$33 BILLION dollars in additional
healthcare costs EACH YEAR

(Scott, 2009)

Worst of all, almost all HAIs can be prevented

Current changes:

- **Health and Human Services (HHS) improve regulatory oversight of hospitals and CMS**
- **HHS to move forward with implementation over 1,200 recommended clinical practices put forth by the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC)**
- **Expand the public transparency of quality outcomes for consumers**
- **Finalization of the HHS HAI Action Plan Tier 2 Modules — which includes Ambulatory Surgery is scheduled for early 2011**

US Government Accountability Office Study

- Study in February 2009 determined reliable, current data, on HAIs in ambulatory care is unavailable
- Prevalence in lapses of recommended practices in ASC is unknown

(GAO, 2009)

GAO recommended the development of a written plan to use a data collection instrument to conduct recurring periodic surveys of randomly selected ASCs.

CMS concurred and many ASCs through out the country have now experienced these random surveys, with many performing very poorly.

Pending ASC Legislature

- **There are over 20 legislative bills affecting surgery centers, among the states currently in session.**
- **Examples:**
 - Required certification of the infection control/preventionist
 - Mandatory hand hygiene compliance rate reporting to public health department available to public
 - Mandatory, health department, state and death certificate reporting for HAIs and MDROs, SSIs, CLRBSI, VAP, UTI
 - Patient consent for use of reprocessed or recycled medical devices
- Mandatory reporting for surgical site infections (SSIs) which occur as a result of surgery in hospitals receiving Medicare payments has been initiated and additional requirements for ASCs are anticipated by January, 2012

Existing legislation

On May 15, 2009, Department of Health & Human Services published the extensively revised State Operations Manual Appendix L– Guidance for Surveyors: Ambulatory Surgical Centers

- **These requirements became effective May 18, 2009 and failure by many ASCs to meet these requirements have resulted in numerous surgery center closings, loss of revenue, and negative public relations for surgery centers which could have been prevented.**

Compliance with these infection prevention/control standards is currently a “condition” for receiving Medicare payments, and historically, third party payors quickly adopt Medicare “conditions” as minimal requirements for contractual reimbursement, typically driven through accreditation standards.

1. Does the ASC have an explicit infection control program?

- **Does the program follow nationally recognized infection control guidelines? (CDC/HICPAC/APIC/SHEA/AORN/AAMI)**
 1. The program is written.
 2. Leadership for the IC/IP program is assigned, ***in writing***.
 3. An Infection Preventionist has been appointed, trained and job description signed.
 4. Governance oversight of the program is clearly documented.

- Does the program follow nationally recognized infection control guidelines? (CDC/HICPAC/APIC/SHEA/AORN/AAMI)

5. There is ***ongoing evidence of IC/IP activities which monitor, evaluate and improve processes and outcomes***

- Addressed population risk assessment
- IP Goals based on risk assessment

6. Does the ASC have a policy/procedure in place to comply with State and local health department disease reporting requirements?

- These vary from state to state.

If asked, would staff know what is reportable and to whom?

2. Role of the Infection Preventionist (IP)

Infection preventionist duties

- **Incorporates current research findings into practice**
- **Participates in professional IP/IC organizations**
- **Demonstrates leadership**
- **Identify patient needs/effective facility care practices**
- **Evaluate IP/IC program annually**
 - Recognize facility accomplishments
 - Set new goals
 - Reports to Medical Advisory Committee
- **Promote “zero tolerance” for HAIs**
- **Emphasize prevention**

3. The IP sets goals and objectives for employee participation in IP/IC

- **Determine staff education needs:**
 - Swine Flu
 - Hand hygiene
 - Safe injection practices
 - Risk assessment knowledge — high-risk procedures, patients, devices, diseases, etc.
 - Annual infection control
- Determine goals for the above education efforts—monitor outcomes
- Assess employee health program needs

Do staff members know which practice guidelines the facility has adopted?

4. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?

- **How does the ASC obtain this information?**
 - Email
 - Post-op patient contact (at 30 days?)
 - Primary care providers follow-up
 - Surgeon notification
 - Other
- Supporting documentation?

Surgical Care Improvement Project

- **Which National performance measures are followed?**

- **Antibiotics**
 - More than 30 minutes before cut time, within one hour
 - Re-dosing patient in OR for long cases
 - Use of antimicrobial recommended in guideline
 - Discontinuation within 24 hours of surgery
- **Glucose control in cardiac surgery**
- **Proper hair removal**
- **Normothermia in colorectal surgery patients**

Are outcomes studied, analyzed and benchmarked for compliance with national benchmarks?

Surgical Site Infections (SSIs)

- SSIs should be counted, trended, and rates should be compared to infection rates for same procedure—
Nation Healthcare Safety Network Report

<http://www.cdc.gov/nhsn/PDFs/dataStat/2008NHSNReport.pdf>

- Quarter-to-quarter, year-to-year
- By facility
- By provider
- Report to *Quality Assessment Performance Improvement (QAPI)* or Medical Advisory Committee (MAC) and Governing Body (GB)
- Improve processes and continue monitoring

Infection Prevention/Control Monitoring

- **At least three tools should be used when SSIs occur:**
 - **Infection Investigation Worksheet —** Each SSI should have comprehensive evaluation, using a tool designed specifically for your ASC
 - **Infection Log —** SSI “indicators” should be monitored through an ongoing log, illustrating commonalities
 - **Infection Trend Report —** Be sure to monitor for obvious: diabetes, OR #, surgeon, scrub tech, circulator, lot numbers
- **IP/IC activities/recommendations should be based upon the data gathered through these, and other tools**

5. Develop Measurable Objectives

Goal	Objective
Reduce post-operative infections	Reduce facility post-operative patient infections by 70% next year
Achieve compliance with Medicare Surgical Infection Prevention Project Objectives	Achieve 99% compliance with >30 minutes, <1 hour <i>pre-cut time</i> administration of appropriate antibiotic

Outbreaks in Ambulatory Care Settings

- **Linked to:**

- Multi-dose vial medications and syringe reuse
- Endoscopy
- Reprocessing techniques
- Improper hygiene
- Inadequate cleaning and sterilization techniques

***Survey your center with CMS Assessment
for Infection Control Practices***

6. Observation for Staff Compliance

Hand hygiene

- Focus on staff involved in patient care — physicians, nurses, CRNAs, anesthesiologist
- What types of hand hygiene products are available in patient care areas?
 - Alcohol-based hand rubs installed in accordance with LSC 42 CFR 416.44 (b)(5)
- Event-related hand hygiene?
- Glove use? When?

According to the CDC, what is the single most important procedure for preventing Healthcare Acquired Infections (HAIs)?

Alcohol hand rub



Antiseptic surgical scrub



Monitor staff compliance with hand hygiene compliance

Compliance with Safe Injection Practices

- Require staff members to review and comply with APIC Safe Injection Practices Position Statement. Monitor for compliance
- Needles — one patient
- Syringes — one patient
- Spike IV bags within one hour of use
- Medication vials **always** entered with new needle
- Medication vials **always** entered with new syringe



Multi-dose injectable medications

- Used for only one patient? *If no:*
 - The rubber septum is disinfected with alcohol prior to each entry — for 3 seconds
 - Dated when opened and discarded within 28 days or according to manufacturer's recommendations, whichever comes first
 - Are not stored or accessed in the immediate areas where direct patient contact occurs

The use of manifolds is prohibited

Specific observation required of staff who perform finger stick testing

- New, single-use, auto-disabling lancing device is used for each patient
- The glucose meter is not used on more than one patient unless approved for multi-patient use
- The glucose meter is cleaned and disinfected after every use



Use and cleaning of equipment is compliant with manufacturers recommendations

- The manufacturers' written instructions for use are the basis for the department's policies and procedures and must be kept up-to-date.
- Manufacturers must validate cleaning/processing and sterilization process with approval from the FDA before availability to market.
- Many of today's instruments have unique cleaning techniques and sterilization cycles.
- Failing to follow these instructions would be indefensible in a lawsuit and may result in survey deficiencies if identified.

7. Single-Use Devices

If single-use devices are reprocessed, is the device:

- Approved by the FDA for reprocessing?
- Reprocessed by an FDA-approved reprocessor?
 - A reused single-use device will have to comply with the same regulatory requirements of the device when it was originally manufactured

*Reuse of single-use devices will result in a
“condition” level deficiency during a
Medicare/Accreditation survey and accounts for many
ASC “Immediate Jeopardy” closings.*

8. Sterilization and high level disinfection of critical equipment

- **Items pre-cleaned according to manufacturer's instructions (ATMI) or evidence based guidelines (EBG) prior to sterilization**
- **Devices and instruments visually inspected for residual soil and re-cleaned prior to leaving decontamination area**
- **What type of sterilization method is used?**

Surveyors should follow instruments through a complete cycle — sterile to sterile?

- **OR to decontamination**

- Is the bio-burden completely removed in pre-treatment?

- **Instruments washed/rinsed moved to packaging/treatment without crossing or re-entering area where instruments decontaminated/cleaned**

- **Packaged or wrapped**

- **Sterilized/high-level processed according to manufacturer's recommendations**

- **Returned to OR (or stored) in a manner that maintains integrity and compliance with standards**

Two Types of Steam Autoclaves

Gravity-Displacement

- In general, longer exposure times, longer drying cycles
- Incoming steam displaces residual air through a port or drain in or near the bottom
- Typical operating temperatures are 121-123 C (250-291 F)
- See manufacturer's recommendations for cycle length

Dynamic-air-removal (Pre-vac)

- In general, shorter exposure times, shorter drying cycles
- Depends on pressure and vacuum excursions at the start of the cycle to remove air.
- Typical operating temperatures are 132-135 C (270-275 F)
- See manufacturer's recommendations for cycle length

Sterilization Cycle Validation Documentation

- For Pre-vac, Bowie Dick Test (air removal) daily
- Biological indicator is performed *at least* weekly and *with all implantable devices* (preferred daily AAMI)
- Chemical indicators are placed in each load
- Each load monitored with mechanical indicators (e.g. time, temperature, pressure)
- Documentation for each sterilizer, up-to-date, including results from each load

To flash or not to flash?

- **Time required for flash sterilization depends on the type of sterilizer and the type of item**
- **It is not recommended as a routine sterilization**
 - **Lack of timely biological indicators to monitor performance**
 - **Absence of protective packaging following processing**
 - **Possibility of contamination during transport to OR**

(Rutala, et al, 2008)

If you MUST flash:

- **Buy more instruments if flashing is required regularly**
- **For occasional flashing:**
 1. **Place equipment for flash sterilization in close proximity to OR to facilitate aseptic delivery to point of use**
 2. **Extend the exposure time to ensure lethality comparable to sterilized wrapped items**
 3. **Use rapid read (one hour) BI for flash-sterilization**
 4. **Use protective packaging that permits steam penetration**
 5. **Buy rigid, reusable containers validated by manufacturer for use with flash cycles**

Semi-critical equipment

High-level disinfect



Or sterilize



Items are pre-cleaned according to manufacturers' instructions or evidence-based guidelines (ATMI) prior to high-level disinfection

Disinfection chemical/equipment maintained according to the manufacturer's instructions (ATMI)

- **Chemicals used are:**

- Prepared ATMI
- Tested for appropriate concentration ATMI
- Replace ATMI
- Documented ATMI

- **Equipment/Sterilizers are tested ATMI**

9. Sanitary Environment

- **Required environmental elements**
 - **Specific cleaning schedule in all areas**
 - **Use of appropriate cleaning products registered with the EPA**
 - **Staff lounge refrigerator/food preparation area**
 - **Ventilation & water quality**
 - **Disposal of regulated and non-regulated waste**
 - **Clean and disinfect areas which are touched and used between patients**
 - **Assign written monitoring to assure appropriate OR cleaning**

Sanitary Environment

- Monitor cleaning:
 - Anesthesia equipment/ carts are cleaned (handles, knobs, towel)
 - Computer keyboard
 - Cords
 - Overhead lights
 - AC intake ducts



The OR



- Personal items in the OR (back packs, purses, cell phones)
- Change gloves, sanitize hands after intubation/extubation
- Prepare tape for intubation with clean gloves and only access the inside of the cart with clean hands
- Disinfect clipper handle, discard heads/blades between cases
- Keep IV tubing off the floor
- PPE worn at appropriate times
 - Staff scrubs
 - Clean head covers
 - No artificial nails
 - No jewelry

Surveyors will observe for evidence standard and transmission based precautions are practiced

- **Appropriate use of gloves, gowns/aprons, masks/face protection**
- **PPE donned and removed according to the CDC**
- **Linen: stored to prevent contamination — solid bottom shelf to prevent splash**
- **Soiled laundry away from clothing or clean items**
- **Place soiled laundry in leak-proof bag at point of use**

Environmental Infection Control

- **ORs cleaned and disinfected after each surgical case or procedure with an EPA-registered disinfectant**
- **ORs terminally cleaned daily**
- **High-touch surfaces cleaned and disinfected with an EPA-registered disinfectant**
- **The ASC has a procedure and written policy to decontaminate gross spills of blood**

Refrigerators and Freezers



- No food
- Record temps of both freezer and refrigerator daily, **twice daily if vaccines**
- Follow-up for temps out of range. Document actions
- **Centralized electronic monitoring or high/low digital thermometers now recommended**

Environmental Management

- **Air filters changed**
 - Dust or mold on AC ventilation ducts
- **Water**
 - Leaks can lead to mold (ceiling, under sinks, behind vinyl wallpaper)
- **Furnishings, floors**
- **Patient stretchers, mattress pads torn, cracked**
- **Floor seams separating in OR**
- **Paint chipped, wallboard damaged**

10. Employee Health Program— CDC Recommendations

Employee Measures

Pre-employment

- Health History
- Communicable disease history
- Screening for vaccines:
Hepatitis B, MMR, Chicken Pox
- Tuberculin Skin Test
- Presence of chronic infection
or disability

Immunization recommendations for HCW

- Hep B
- Influenza
- MMR
- Varicella
- Tetanus
- Pertussis
- Rabies (in select settings)

CDC, 2009

Exposure Evaluation/Counseling

If exposed to BBP infection

- Hepatitis B, C, D, HIV
- Testing
- Prophylaxis
- Counseling
- Patient Informed consent**

Evidence of

- Conjunctivitis—restrict from direct patient care for duration of symptoms
- H1N1-healthcare personnel who develop a febrile respiratory illness should be excluded from work for seven days or until symptoms have resolved, whichever is longer

Prevention and Control

- **Annual facility TB risk assessment**
- **Employee screening program**
- **Annual TB education for HCW**

Summary IP/IC Program

1. Assign Leadership

- a. Document governance oversight and approval

2. Written plan

- a. Infection prevention, surveillance and control
- b. Monitor, report, revise
- c. Document governance oversight and approval

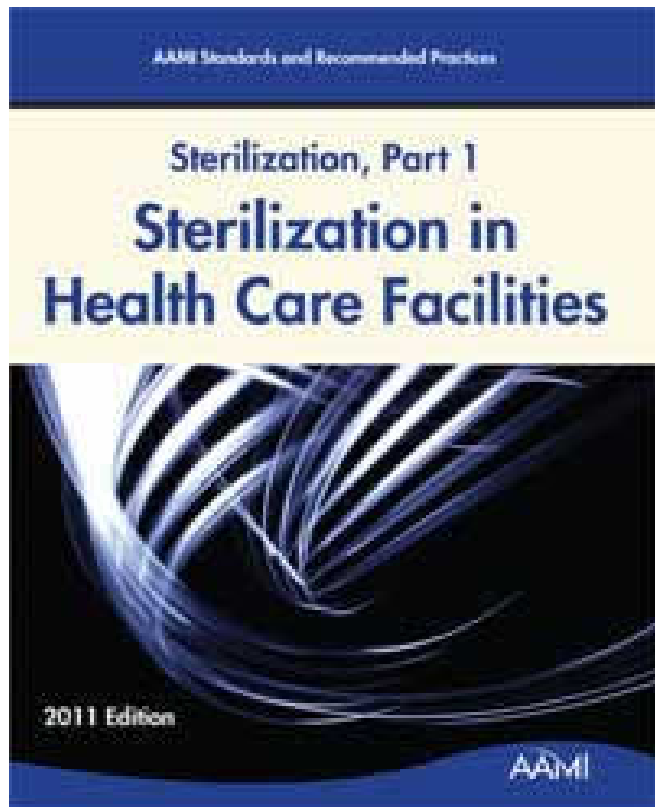
3. Sanitary Environment

- a. Monitor environment
- b. Standard Precautions
- c. Instrument/equipment cleaning, disinfection, sterilization

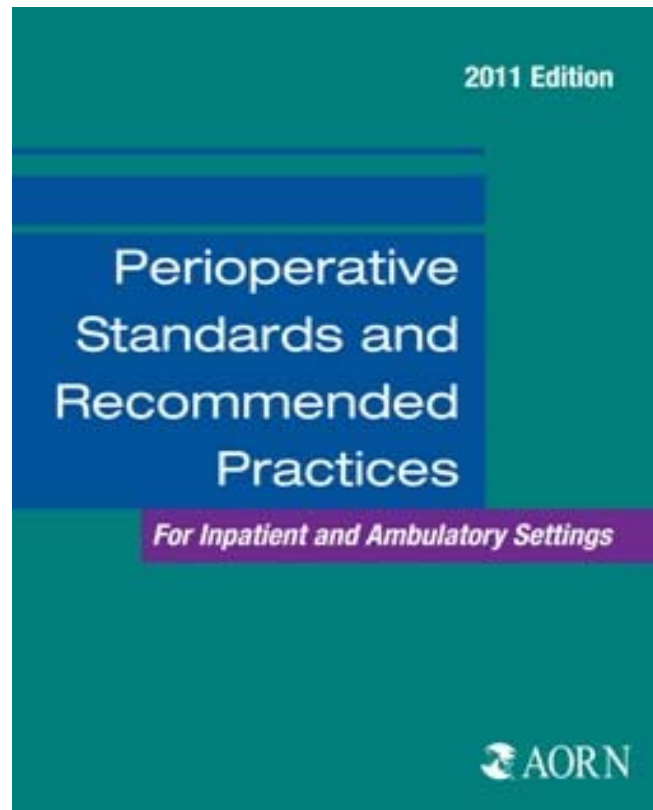
4. Employee Health

Critical Resources

Critical Resources AAMI Standards



AORN Standards





Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Reuse of single-use devices will result in a “condition” level deficiency during a Medicare/Accreditation survey and accounts for many ASC “Immediate Jeopardy” closings.

**Resource for consulting services from
the experts in infection prevention:**

www.apicconsulting.com

References:

APIC <http://www.apic.org>

APIC Position Paper: Safe Injection, Infusion and Medication Vial Practices in Healthcare

Infection Prevention in Ambulatory Care: Meeting CMS Conditions for Coverage

Basic Elements of Infection Prevention

Employee Health

Cleaning, Disinfection and Sterilization in the Ambulatory Care Setting

It's All About Prevention

Role of the Environment in Infection Prevention

Pending ASC Legislation for 2009

Infection Prevention and Control Solutions for Ambulatory Care

http://www.apic.org/Content/NavigationMenu/MemberServices/AmbulatoryCare/Ambulatory_Care.htm

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

Battaglio, J. (2009) Preventing Infection in Ambulatory Care, Volume 1, Issue 1. APIC Advances Efforts to Stop Unsafe Needle Practices P 1.

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U.S. Department of Health & Human Services. (2009) HHS Action Plan to Prevent Healthcare-Associated Infections: Executive Summary.
<http://www.hhs.gov/ophs/initiatives/hai/exsummary.html>

United States Government Accountability Office: Report to Congressional Requesters. Health-Care Associated Infections. (2/2009)

**Special thanks to
Carol Hiatt, RN, LHRM, CASC**

**Surgery Center Consulting Services
www.surgerycenterconsultingservicescccs.com**



1-866-410-1751

www.LaserSpineInstitute.com

E-mail: info@laserspineinstitute.com

Dotty Bollinger, RN, JD, CASC, LHRM
Chief Medical Operations Officer

Thank You

INFECTION CONTROL

SUBJECT: MRSA

POLICY:

Persons with a known history of MRSA, who may be colonized but do not have an active MRSA infection, are eligible for elective surgery at LSI following proof of negative MRSA screening and/or decolonization.

Persons with known active MRSA infections will not be accepted as elective patients due to the risk posed to the patient with the infection as well as other patients and visitors. They may be reconsidered for surgery only after completing treatment and resolution of the infection.

Persons with a surgical site infection following surgery at the Center, who are returning for I&D/ washout/cultures, will be considered to be at high risk for MRSA and will be scheduled as “last case” on the surgery schedule to further minimize the risk of nosocomial MRSA transmission in the Center.

1. Preliminary screening questions regarding signs/symptoms of current or recent infection, or any history of an antibiotic resistant infection, will be asked during initial scheduling discussion with the patient. Patients with a stated positive history will be routed to the Medical Clearance staff for further inquiry, screening, work-up, treatment, and/or decolonization as indicated.
2. Patients with active infections will not be scheduled for surgery at the Center until resolution of the infection is verified by the patient’s primary physician and/or LSI Medical Staff.
3. If a patient fails to disclose a positive history and arrives in the Clinic for H&P and preop work-up, at which time a practitioner discovers a positive history without current infection, a screening test (nasal swab) will be completed and surgery will be delayed until a “negative” test result is received (typically 48 hours). If the test returns positive, the patient must be sent home or sent out for decolonization before returning for surgery.
4. If a patient is admitted to the Center for a procedure or surgery, and is found to have signs and/or symptoms of infection such as fever or draining wounds, the surgeon and supervising anesthesiologist will be notified immediately for evaluation and surgical decision.
5. **It is important to note that Universal Precautions, conscientious hand hygiene and current environmental cleaning procedures are sufficient to prevent the transmission of MRSA within the facility. Not all patients that are colonized and/or who have active MRSA infections will self-report and it is highly likely that many MRSA patients will go undetected through admission, surgery and discharge.**

6. If a patient with a postoperative wound infection requires reoperation at the Center for I&D/washout/cultures, appropriate levels of caution should be maintained in the Center according to infection control guidelines
 - a. Patient should be scheduled for last case of the day if possible.
 - b. Non-disposable items (bed, BP, equipment, etc.) coming in contact with the patients shall be thoroughly disinfected with germicide and/or sterilized as needed per current cleaning and decontamination procedures.
 - c. When staff is in direct contact with an infectious patient in the Center, they shall adhere to universal precautions regarding personal protective equipment and place particular emphasis on hand hygiene.
 - d. Assure proper disposal of disposable supplies, needles, syringes, etc., used with infectious patients.
 - e. The care areas and OR occupied by the MRSA patient will be thoroughly cleaned as would be the case for any patient.
6. The Director of Nursing and Infection Control Nurse will be responsible for monitoring all the infection control procedures and for tracking MRSA patients.

SURGICAL WOUND CLASSIFICATION***Classification***

- I **Clean Wound:** No apparent inflammation
- II **Clean Contaminated Wound:** Infection discovered, but contained
- III **Contaminated Wound:** Gross contamination or spillage from G.I. tract
- IV **Dirty or Infected Wound:** Acute inflammation with pus formation, break in aseptic technique

Breaks in Technique or Contaminating Factors (Indicate letter on form below, if applicable)

- A. Improper hair covering E. Improper hand scrub H. Improper surgical site prep
- B. Hole in glove F. Skin rash, lesion, boil I. Patient's body feces, unbathed, etc.
- C. Heavy traffic pattern G. Wound exposure longer J. Contaminated field, hair, etc.
- D. Improper mask covering than expected

Patient Code _____ Age _____

Classification:

Date _____

I Clean Wound _____

II Clean Contaminated Wound _____

Surgeon Code _____

III Contaminated Wound _____

Anesthesia Staff Code _____

IV Dirty or Infected Wound _____

O.R. Technician Code _____

Contaminating Factor _____

Circulating Nurse Code _____

Culture in O.R.? Yes _____ No _____

Operating/Procedure Room # _____

Postop Follow-Up:

Temp Elevation _____

Purulent Drain _____

Start: _____ AM/PM

Cultures _____

Finish: _____ AM/PM

Wound Infection _____

CENTER _____

OBSERVER _____

DATE _____

Health Care Worker (HCW) Codes:
1 = Surgeon 2 = Nurse 3 = Surgical Technician 4 = ARNP/PA 5 = Anesthesia 6 = MA 7=LPN
HR = Hand Rubbing HW = Hand Washing

	HCW Code	Hand Hygiene Before Patient Contact (Mark the appropriate column)			Gloves Worn if Required (Mark the appropriate column)			Hand Hygiene After Contact with Patient, Equipment, Environment, or Removing Gloves (Mark the appropriate column)			Hand Hygiene Before and After			
		See Key	HR	HW	No	Yes	No	N/A	HR	HW	No	Yes	No	
1														
2														
3														
4														
5														
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7														
8														
9														
10														
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17														
18														
19														
20														
Totals								Totals						
Percent Adherence*								Percent Adherence *						

- For glove use : Total number of “Yes” ÷ (Number of rows w/data – Number of N/A) x 100
- For Hand Hygiene: Total number of “Yes” ÷ Number of rows w/ data x 100