CHAPTER 3
OPERATING ROOM

Operating Room and Central Processing Division

The operating room functions to provide a controlled environment for the performance of surgical procedures. Surgical wound infections are the second most common nosocomial infection and may involve either the incision or adjacent structures. Most surgical wound infections result from microbial contamination (endogenous or exogenous source) of the wound during surgery. Operating room procedures are designed to provide the maximum reduction of exogenous microorganisms that could contaminate the surgical wound. Personnel and their compliance with surgically aseptic procedures are a critical component in the prevention of surgical wound infections.

Infection Control Practices:

Employee Health

- Careful attention to employee health, safety, and personal hygiene will minimize the potential for acquiring or transmitting disease.
- Personnel working in the OR shall be free from active infection.
- Will keep vaccinations current as vaccinations provide backup protection when there has been a failure in work practices.
- Individuals exhibiting signs and symptoms of an infection must report immediately to their supervisor. The supervisor will refer them to Occupational Health for evaluation and work duty status.
- All personnel suspected of having communicable infections shall be excluded from working in the OR until they have been cleared by Occupational Health.
- An employee who feels he/she has been exposed to a communicable disease or occupational exposure (i.e., needle stick or sharps injury) must report immediately to his/her supervisor who will send the employee to Occupational Health. If the exposure occurred on PMs, nights, or weekends, the individual will be evaluated in the Emergency Room, but must report to Occupational Health the next working day.
- Will become familiar with and adhere to policies set forth in the Infection Control Manual.
- Will use protective barriers to reduce the risk of skin and mucous membrane exposure to potentially infectious materials.
- Will follow hospital policy on “Standard Precautions” for protection against blood borne pathogens and demonstrate competence in the prevention of transmissible infections.
- Will use contact, droplet, or airborne precautions as appropriate when providing care for patients who are known or suspected to be infected or colonized with microorganisms.
- Will report promptly any suspected communicable diseases, occupational injury, or infectious exposures to Occupational Health for evaluation, treatment, and follow-up.
- Will adhere to good hygiene practices. Hair, body and nails should be clean at all times.
- Neither nail polish nor artificial nails shall be worn. Fingernails should be kept short and clean and should not extend beyond the fingertips.
- Will practice frequent and thorough handwashing with appropriate soap before and after each patient contact.
- Will utilize work practices designed to minimize risk of exposure to pathogens.
- Work practice controls include prohibition of eating, drinking, smoking, applying cosmetics or lip balm, and handling of contact lenses in work areas where there is reasonable likelihood
of occupational exposure to bloodborne pathogens. Activities involving hand-to-nose, hand-to-mouth, or hand-to-eye action can contribute to indirect transmission.

- Will report suspected trends or problems related to infection control to the Infection Prevention and Control Department.

Surgical Attire

- Scrub clothing is worn to promote a high level of cleanliness and hygiene within the surgical environment because the human body is a major source of microbial contamination. Surgical attire helps contain bacterial shedding and promotes environmental control. The rationale behind this practice is to prevent the spread of infection from staff to patient. Proper operating room attire includes clean scrub suit (with shirt tucked into pants to prevent shedding of body scurf) donned in a designated dressing area prior to entering the semi restricted or restricted areas of the facility.

- Appropriate, clean attire minimizes the introduction of microorganisms and lint from personnel to surgical patients and to the environment. Controlled laundering of garments contaminated by blood or body fluids reduces the risk of transferring pathogenic microorganisms from the health care facility to home and family. Other garments should be contained completely within or covered by the surgical attire. Clothing that cannot be covered by the surgical attire should not be worn.

- All personnel entering the restricted areas of the OR suite, decontamination, preparation, sterilization and sterile storage areas will be attired in operating room scrub attire provided by and donned at NMCP. Home laundering will not be done. Taking previously worn, soiled, or contaminated surgical attire into the home can result in the spread of contamination to the home environment. No one in street clothes will be permitted in the suite at any time. Parents/visitors are allowed in the restricted areas, with coveralls, mask, cap, and shoe covers.

- If indicated, a head cover and beard cover shall be worn to fully cover hair on head and face. The head cover or hood should be designed to minimize microbial dispersal. Hair acts as a filter and collects bacteria. A bald or shaved head is covered to prevent the shedding of squamous cells. Disposable bouffant and hood-style covers are preferred. Head cover should be applied before the scrub suit so that hair does not touch the scrub suit while it is being donned. Single use headgear should be removed and discarded as soon as possible after daily use.

- Masks will be worn at all times in the operating rooms and sub-steriles. A single surgical mask will be worn in surgical environments where open sterile supplies or scrubbed persons are located. A mask should fully cover both mouth and nose and be secured in a manner that prevents venting. A surgical mask is worn if sterile instruments are exposed, or if an operation is about to begin or underway. Masks will be changed after each case and not worn dangling around the neck. Masks should be removed carefully by handling only the ties and discarded immediately to avoid cross-contamination.

- Sterile gloves are worn for sterile procedures and medical, nonsterile gloves are recommended for nonsterile activities.

- Protective eyewear, masks or face shields must be worn when splashing or spraying is likely.

- Comfortable supportive shoes should be worn for personal safety. Cloth shoes should not be worn because they provide little protection from spills or accidentally dropped items. Shoe covers are considered part of PPE and should be worn when it can be reasonably anticipated that splashes or spills may occur. Foot attire has no proven significance in reducing the
incidence of surgical site wound infections; the primary reason for its use is to facilitate sanitation. Shoe covers must be discarded prior to leaving the surgical area.

- A surgical team wears sterile gowns after a hand surgical scrub is performed. Gowns must be resistant to penetration by moisture. Gown fronts are considered sterile from shoulder to table level on the front and on the front of the sleeve (axillary area is contaminated). Sterile gloves are worn by the surgical team. Gown and gloves must be changed when punctures, contamination, or strike through occurs.

- Scrub suits must be changed when visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials. All attire will be fresh each day and changed if it becomes wet or soiled.

- When leaving the OR suite, a clean cover gown worn backwards and tied or buttoned lab coat is to be worn over the scrub suit. Caps, beard covers, masks, and shoe covers are to be removed and replaced with fresh ones when returning to the operating room suite.

- All personnel entering the semi restricted and restricted areas of the surgical suite should confine or remove all jewelry and watches. Rings should be removed because rings can harbor organisms that cannot be removed during hand washing. Other jewelry such as watches, earrings, bracelets, necklaces, and piercings should be removed or totally confined within the scrub attire due to the possibility jewelry could fall onto the sterile field or into a wound. Necklaces that are not confined could contaminate the front of the sterile gown. Jewelry must meet the Navy standard, which is 1 ring each hand, plus wedding/engagement ring set. Only one watch and bracelet are authorized. One necklace can be worn, but not visible. No jewelry is authorized while a person is scrubbed in on a surgical case or while prepping or positioning a patient.

- Fingernails should be kept short, clean, natural and healthy due to the subungual regions harboring the majority of microorganisms found on the hand. Nail polish that is obviously chipped or worn longer than four days is associated with the presence of greater numbers of bacteria. Artificial Nails should not be worn. Studies have shown that artificial nails on healthy hands increased the risk of surgical site infection.

### Surgical Drapes

- Draping is the process of covering with sterile barrier materials the non-sterile area immediate to and surrounding the operative site. Drapes are used as barriers to prevent microorganisms outside the operative area from entering a wound.

- Draping is done primarily for the protection of the patient, the surgical site, and the sterile field.

- Draping creates an aseptic barrier between the surgical incision and the patient’s non-prepared skin, guarding the wound from bacteria.

- Sterile drapes are used to establish a sterile field around or close to a surgical site.

- Disposable surgical drapes are used.

- Drapes should be resistant to the passage of blood and fluids (resistant to strike through), impermeable to moist microbial penetration, including viruses, resistant to tearing, puncture, or abrasion, lint free, flame resistant/flame retardant and antistatic, free of toxic ingredients, porous enough to maintain an isothermic environment appropriate to body temperature and easy to use.

- The disposable drapes are obtained sterile from the factory in protective wrappers. Prior to use, the wrappers are checked closely for damage to ensure sterility.
Drapes are handled as little as possible and should not be waved or fanned in the air.

Drapes are held high enough to avoid touching non-sterile areas until they are over the area to be draped.

Sterile gloved hands are protected from contact with the patient by placing them under the drape (cuffing) as each drape is placed.

Do not move or rearrange drapes once placed.

Linens are received, inspected, and processed in accordance with Joint Commission requirements and AORN standards.

Disposable drapes that most closely conform to the needs of the procedure are chosen. Drapes are used in accordance with factory recommendations.

AAMI’s Technical Information Report outlines four categories of barrier (draping) materials:

- Liquid resistant (inhibits the penetration of liquids)
- Liquid barrier (prevents the visible penetration of liquids)
- Microbial barrier (prevents the penetration of microorganisms)
- Liquid proof (prevents the penetration of liquids and microorganisms)

Surgical Environments

Floors, Walls and Ceilings

- The surface of all floors must not be porous but instead be suitably hard, wear resistant, seamless, non-conductive, and easy to clean.
- Floor drains should not be installed. Drains in cystoscopy rooms should contain a non-splash horizontal-flow flushing bowl beneath the drain plate.
- Walls should be one continuous surface, easy to clean, and free of seams.
- Ceilings should be a minimum of 10 feet high, hard, nonporous, fire resistant, waterproof, stain proof, seamless, non-reflective, and easy to clean.

Temperature and Humidity

- Temperature should be maintained between 68°F to 73°F (20°C to 23°C) within the operating room suite and general work areas in sterile processing.
- Decontamination area temperature should be maintained between 60°F to 65°F (16°C to 18°C)
- Relative humidity should be maintained from 30% to 60% within the perioperative suite, including operating rooms, instrument processing areas, and sterilizing areas. A relative humidity of below 70% should be maintained in sterile storage areas.

Airborne Contamination and Ventilation Systems

- Airborne Contamination: One of the major goals of the surgical team is to reduce or minimize the counts of bacteria-carrying particles in the air.
- Ventilation Systems: Should be designed so that airflow patterns will not allow air contaminants to enter clean areas. Air should flow from areas of positive pressure to areas of negative pressure.
- The quality of air entering the operating rooms should be carefully monitored.
- Air should be filtered through two filters; the first filter should be rated as 30% efficient and the second at 90% efficient.
• Operating Room ventilation is maintained at positive pressure with respect to the corridors and adjacent areas because positive pressure prevents airflow from less clean areas into more clean areas. All air should be introduced from the ceiling and exhausted at the floor.
• Operating Room doors should be kept closed except as needed for passage of equipment, personnel or the patient to reduce the microbial level in the air.
• A minimum of 20% of the incoming air (three air changes per hour) should be from the outdoors.
• Operating rooms should have a minimum of 15 air exchanges per hour with a recommended range of 20 to 25 exchanges.
• Soiled decontamination and sterilizer loading/unloading should have a minimum of 10 air exchanges per hour.
• Sterile storage, preparation and packaging should have a minimum of 4 air exchanges per hour.
• Free standing fans, humidifiers, or dehumidifiers should not be used in the operating room or sterile processing due to disrupted air-flow patterns resulting in contamination of the sterile field.
• The soiled and decontamination area of the Central Processing Department should be designed so that air flows into the area (negative pressure), with a minimum of 10 air exchanges per hour. Air from rooms or areas under negative pressure should be exhausted to the outside via a non-re-circulating system.

Traffic Control
General:
• The surgical suite is divided into three designated areas that are defined by the physical activities performed in each area. Increasing environmental controls and surgical attire as progression is made from unrestricted to restricted areas decreases the potential for cross-contamination.
• The unrestricted area includes the central control point established to monitor the entrance of patients, personnel, and materials. Street clothes are permitted in this area and traffic is not limited.
• The front desk, patient hold, and supply are considered semi-restricted support areas. Street clothes may be worn in these areas.
• Semi-restricted areas include the peripheral support areas of the surgical suite. This area includes storage areas for clean and sterile supplies, work areas for Central Processing, scrub sinks and corridors leading to the restricted areas of the surgical suite. Traffic in semi-restricted areas is limited to authorized personnel and patients. Personnel are required to wear surgical attire and cover all head and facial hair.
• The care of the patient during surgery requires movement of patients, personnel, and material within the surgical suite. Planning and controlling these movements assist in the containment of contamination. Only authorized personnel are allowed in the restricted areas. “Authorized” personnel are those assigned to Surgical Services to include:
  • Perioperative Nurses and Surgical Technologists
  • Anesthesiologists, their residents, CRNAs, SRNAs, and Anesthesia Technicians
  • Surgeons, their residents, interns, and medical students
• The restricted area includes the Operating Rooms (ORs), procedure rooms and clean core areas. Proper surgical scrub attire, hair coverings, and name identification are mandatory in the restricted areas. Masks are required where open sterile supplies or scrubbed persons are located. Unnecessary traffic is not permitted. All doors must be kept closed except as needed for passage of equipment, personnel, and patients. All staff traffic to and from an operating room will be via the sub-sterile door. Talking and the number of personnel allowed to enter the operating room, especially with a surgical procedure in progress, will be kept to a minimum.

• Persons entering the semi-restricted or restricted areas of the surgical suite for a brief time for a specific purpose, such as parents or biomedical engineers, should cover all head and facial hair and may don either freshly laundered surgical attire or a single-use coverall suit designed to totally cover outside apparel.

• Patients should wear clean gowns, be covered with clean linens, and hair coverings.

• Surgical supplies prepared for surgical procedures outside the surgical suite (e.g. in Central Processing Department, CPD) should be transported to the surgical suite to maintain cleanliness and sterility and to prevent physical damage. Protect items from contamination, physical damage, and loss during transportation.

• Sterile supplies and equipment should be removed from external shipping containers and web edged or corrugated cardboard boxes in the unrestricted area before transfer into the surgical suite. External shipping containers may collect dust, debris, and insects during shipment and may carry contaminants into the surgical suite.

• Soiled supplies, instruments, and equipment should not re-enter the clean core area. Contaminated items should be in closed, covered carts or containers for transport to the decontamination area.

• Decontamination areas and soiled linen areas should be separate from personnel and patient traffic areas.

• Separate clean and sterile supplies and equipment from soiled materials by space, time, and traffic patterns to decrease risk of infection.

Observation

• Observation of surgical procedures for medical education purposes is an integral part of a teaching institution. Visiting surgeons, hospital staff, nursing students and product representatives may receive authorization for observation/participation on a case by case basis. Requests are submitted by the sponsor to the Head, Operating Room Services via the Director, Surgical Services no later than 24 hours in advance.

• All requests approved must also have the approval of the individual room’s crew or nurse, anesthesia personnel, and surgeon.

• It is the sponsor’s responsibility to inform the patient of the observing personnel.

Handling of Infectious Waste, Linen and Sharps

• Infectious waste and all potentially contaminated disposable items are disposed of in accordance with hospital policy.

• Soiled linen will be placed in an impervious linen bag of sufficient quality to contain used/soiled linen.

• Needles, syringes, and sharps are to be disposed of uncapped and uncut, into puncture-resistant sharps containers, being careful to avoid injury. Sharps used during a surgical
procedure are placed in a needle pad on the back table and discarded at the end of the procedure in appropriate sharps containers.

Intra-operative Infection Control

Responsibility of circulator:

- Hand hygiene is the most important factor in preventing the spread of infection.
- Clean, non-sterile gloves should be worn when touching blood, body fluids, secretions, excretions, and contaminated items. Change gloves between tasks and patient procedures.
- Limit traffic in room.
- Walking outside the periphery of the sterile field or leaving and returning to the OR in sterile attire increases the potential for contamination.
- Talking is kept to a minimum in the presence of the sterile field to reduce the spread of moisture droplets.
- Wear a protective apron or cover gown if soiling with blood or body fluids is anticipated.
- A mask and eye protection or a face shield is to be worn at any time patient care activities are likely to generate sprays or splashes of blood or body fluids, secretions or excretions. All primary scrub techs will wear eye protection.
- Maintain a clean environment during procedures.
- Single-use items should be discarded after use. Reusable equipment must be cleaned and re-processed to ensure safe use for another patient.
- Linens soiled with blood, body fluids, secretions, or excretions should be handled in a manner to avoid skin and mucous membrane exposure, clothing contamination and transfer of microorganisms to other patients, personnel, and the environment.

Handling of Specimens:

- Healthcare workers should receive specific instructions regarding the handling and transportation of cultures and specimens.
- Retrieve cultures and specimens from the scrub technician wearing gloves or deliver specimen to container held by circulator. Label and appropriately process the specimen.
- Contamination of the outside of culture and specimen containers with blood or other body fluids should be avoided. If the specimen container is removed from the field, the exterior of the container should be disinfected with an approved hospital grade disinfectant before the specimen is removed from the surgical suite.
- Because cultures and specimens are considered potentially infectious, all personnel should use gloves when handling them.
- Hands should be washed thoroughly after gloves are removed.
- Standard precautions should be employed and specimens should be put in leak-proof containers to ensure safe handling, processing, storage, transport, and shipping.

Responsibilities of scrub technician:

- Remain gowned and gloved while breaking down and disposing of instruments, utensils, trash, linens, and sharps.
• Needles, scalpels, and other sharps should be handled in a manner to avoid injury. Dispose of all sharps used on the surgical field by placing into the red sharps container.

• Discard suction tubing. A closed suction system is used. Suction liners are taped shut and placed in infectious waste bags. Wear personal protective attire if indicated.

Housekeeping Requirements.

Policy:
• All cases are considered “potentially infectious”. No special “quarantine” procedures of operating rooms or operating room personnel involved with “septic” procedures are practiced or considered necessary. Clean up between clean and/or dirty cases is the same. The “confine and contain” principle of operating room management shall be practiced therefore maximally reducing the dissemination of contaminated materials throughout the operating room suite.

• The patient should be provided a clean, safe environment. Health care-associated infections (HAI) have been linked to external sources, which can include environmental surfaces. The risk of infection from pathogenic organisms on environmental surfaces is due not only to their presence but to their ability to survive on and be transferred to many surfaces.

• Sanitation protocols for cleaning and disinfection are required before, during, and after each procedure. Environmental cleaning is the framework and basis for all aseptic practices.

• Measures should be taken to prevent vermin infestation. Remove food sources and any environment that attracts pests and keep doors and windows closed.

Cleaning before procedures:
• Proper cleaning reduces the amount of exogenous microorganisms, dust, and debris in surgical environments, and it helps to reduce airborne contaminants. Rooms should be visually inspected prior to bringing in any carts or supplies.

• All surfaces within the OR, including furniture, surgical lights and equipment should be damp-dusted before the first scheduled surgical procedure of the day. Damp dust with a lint-free cloth and an approved hospital grade disinfectant. Plasma screens and monitors should be cleaned according to manufacturer’s guidelines.

• Lights and overhead tracks become contaminated quickly with dust, debris, and microorganisms, which can fall onto sterile surfaces or into wounds during surgical procedures and should be cleaned on a daily basis before the first procedure of the day.

• String and microfiber mops and cleaning cloths should be changed after each use. Used cleaning mops or cloths should not be returned to the cleaning solution container.

Cleaning during procedures:
• During a procedure the practice of “confine and contain” should be practiced to limit contamination. Use appropriate PPE when handling contaminated items.

• Accidental spills of contaminated debris in areas outside the surgical field should be cleaned promptly with an approved hospital grade disinfectant.

• Soiled sponges are placed in a plastic lined bucket or plastic pouch and not on a draped table or spread out on an impervious barrier on the floor.
• All disposable sharps are considered infectious waste and should be placed in puncture-resistant containers and labeled as biohazardous waste.
• Contaminated disposable items used in patient care are discarded in leak-proof, tear-resistant containers.

Cleaning between and after procedures.
• All trash is collected in sturdy plastic or impervious bags.
• Damaged or worn coverings should be replaced.
• Perform in each individual operating room beginning with the first case of the day and between consecutively scheduled surgical cases.
• Using appropriate disinfectant and a clean cloth, damp dust all lights and vertical surfaces of all furniture and fixtures in the room. All reusable items such as pneumatic tourniquet cuffs should be cleaned with an approved hospital grade disinfectant. All receptacles such as bins, kick buckets, and pails should be cleaned and disinfected.
• All horizontal surfaces and surfaces that have come in immediate contact with the patient, body fluids, or with electrical or laser plume are cleaned with an approved hospital grade disinfectant.
• Clean any areas of the room, other than those specified which have become soiled with blood, irrigation fluids, etc., during the just completed case.
• Move furniture as necessary, dispense cleaning solution over the entire area of the floor, and areas soiled with blood or bodily fluids or gross contamination. Allow a 3-5 minute contact time for disinfectant. Using Wet-Vac, remove the cleaning solution from the floor.
• The OR bed is cleaned and all surfaces and mattress pads are wiped with an approved hospital grade disinfectant. Particular attention is given to all surfaces of the OR bed, mattress, and positioning aids where contamination with blood or fluids may have occurred. The OR bed is moved to the periphery of the room so that access is gained to the center of the room for cleaning.
• Move all furniture to the other side of the room and repeat the previous steps on the newly exposed floor area.
• After room is cleaned, gloves are removed and hands are washed and the room is prepared for the next patient.
• Replace all furniture to its correct location.
• Set out clean kick bucket, linens, covers on arm boards, clean linen hamper, instrument breakdown tray, and suction bottle.
• Place clean linens on operating table.

Terminal cleaning:

Perform in each individual operating room every 24 hour period if the room has been opened and used for a surgical case. The decontamination process begins at the highest-level (light tracks, ceiling fixtures) and progresses downward (kick boards and floor).

• Unused rooms should be cleaned at least once every 24 hours
• Using a clean cloth and appropriate disinfectant, thoroughly wipe down operating room lights and light tracks.
• Sponge mop the bulkheads using appropriate disinfectant and water solution prepared in buckets.
• Move all furniture to one side of the room.
• Using the sprinkler can, sprinkle the cleaning solution on the floor. This solution shall be allowed to remain on the floor (3-5 minutes) while the furniture is being cleaned.
• Using clean cloth and disinfectant solution, wipe down all surfaces of all furniture. Room fixtures are also to be wiped down (windowsills, x-ray view box, tape dispenser, operating lights, control box, etc.).
• All room equipment is to be wiped down. Special attention should be given to electro-surgical generator, foot pedal, suction equipment, control table, sponge scale, positioning gear table parts, wheels, and pads.
• Scrub buff the floor and wet vacuum the floor.
• Move all furniture to the opposite side of the room. Scrub buff and wet vacuum the remaining floor area as previously described.
• Return all furniture to its correct location.
• Replace kick bucket, liners, covers on arm boards, clean linen hamper, instrument breakdown tray, and suction bottle.

Field day:
Total cleaning of any specific area including hallways, floors, substeriles, scrub/utility areas, and sterile storage areas. All areas and equipment in the surgical suite should be cleaned according to an established schedule.

• All refrigerators and ice machines should be cleaned on a routine basis.
• Aerators on faucets should be cleaned and disinfected weekly by removing the aerator, scrubbing with detergent and brush and immersing in disinfectant.
• Eye wash stations should be cleaned and checked weekly to ensure that they are in working order.
• Perform field day on every area of the MOR suite (inner and outer) once each week.
• Sponge mop the ceiling using appropriate disinfectant solution.
• Dust all vent covers.
• Dust thoroughly the sterile supply cabinet inside and out within the operating room and check all gear for proper expiration date.
Care of Patients with Tuberculosis in Operating Room

Patients with suspected or confirmed tuberculosis treated in the MOR require Airborne Precautions.

Only emergency or medically necessary surgery is performed on a patient with suspected or confirmed tuberculosis disease. Elective operative procedures on patients with tuberculosis should be delayed until the patient is no longer infectious.

If at all possible, patients with tuberculosis should be scheduled at the end of the day to limit risk to other patients and healthcare workers. Perform the procedure with a minimal number of personnel.

HEPA respirators or N-95 respirators are indicated for all persons entering the OR room for respiratory protection. Valveless HEPA respirators or N-95 respirators will be worn in the OR setting to protect the sterile field.

The doors to the OR will be kept closed and the number of personnel allowed in the OR will be kept to a minimum.

Tuberculosis patients must be recovered in a negative pressure ventilation room and personnel will follow Airborne Precautions and wear N-95 respirators. Patients should then be transported to a negative pressure ventilation room as soon as possible. The patient will have both nose and mouth covered with a regular surgical mask during transport.

Personnel performing environmental cleaning and disinfection in the room of a patient who has an airborne disease must use a properly fit tested N95 mask or powered air purifying respirator until complete air exchange has been achieved.

The period of time required for the ventilation system to achieve a 99.9% air exchange should be noted, for example 28 minutes for a 15 air-exchanges-per-hour cycle.

Access to the room should be restricted until the 99.9% air exchange has been completed.
Central Processing Division

The Central Processing Division (CPD) recognized its responsibility for infection control, realizing that this is an integral part of the total care of the patient. CPD’s primary goal is to provide the highest quality of support so as to contribute to the total care of the patient. CPD will coordinate its activities with all departments in the hospital in order to provide the highest standard of care uniformly throughout the hospital. CPD's infection control guidelines provide for standardized policies and procedures for receiving, decontaminating, packaging, sterilizing, storage, and issue of instrumentation and other medical equipment. Sound principles of infection control will be practiced on a daily basis.

Personnel Policies

Clothing and other requirements:

- Scrub attire in accordance with NAVMEDCENPTSVAINST 1020.1 including waterproof apron, hair cover, gloves, eye protection/face shields and masks (as work requires) shall be worn while working in the decontamination areas.
- Persons working in any other part of CPD, except the decontamination area, will wear scrub attire, hair covers, and shoe covers (with the exception of dedicated work area shoes).
- All personnel from other departments desiring entrance to CPD will be properly attired and request entrance. If not properly attired or if they have no need to be in the area, entrance will be denied.
- All repair and maintenance personnel will observe the dress code for the area in which they are working.
- Under no circumstances shall street clothes be worn in the CPD area.

Food and beverage consumption:

- Food and beverages will only be allowed in CPD office spaces in covered containers.
- Smoking is prohibited in this facility.

Personal hygiene and hand washing:

- All personnel will practice frequent and thorough hand washing with an appropriate soap.
- Personnel working in CPD shall be free from active infection.
- All personnel shall adhere to good hygiene practices, such as daily bathing and wearing a clean scrub uniform.
- Fingernails must be kept short (not beyond fingertip) and clean.
- All personnel handling contaminated items will wear disposable gloves.

Employee illness/exposure:

- All personnel suspected of having communicable infections shall be excluded from working in CPD until they have been cleared by Occupational Health.
- An employee who feels he/she has been exposed to a communicable disease (i.e., occupational injury via needlestick/sharps) or hazardous chemical exposure (i.e., cleaning/decontamination solutions) should report immediately to his/her supervisor who will send the employee to the Emergency Room for evaluation.
Education:

- Basic training in aseptic technique for all CPD personnel must be provided and documented in education files.
- Periodic infection control programs will be provided and documented on no less than a quarterly basis.

Traffic Control

Flow

- All personnel will be taught the proper flow of traffic within CPD. Passage between the areas is to be kept to a minimum and requires knowledge of proper dress codes.

Receiving/decontamination flow pattern:

- Used trays and equipment must be returned free of gross contaminants to the decon area. These items should be transported to CPD in an impervious bag or equipment cart.
- All used trays will be jointly inventoried and a “Gear Requisition/Receipt” form will be completed and signed by both the CPD and departmental representative before the gear is accepted. A copy of this form will be given to the departmental representative and a copy kept for CPD files.

- All instruments and equipment received from clinics and the MOR will undergo manual decontamination and a minimum of a ten minute enzymatic soak. Instruments which are grossly contaminated will follow the enzymatic soak with processing in the ultrasonic cleaner. Lastly, the instruments will be processed through the washer disinfector.

- Linen bags and trash shall be emptied at the end of each shift. All tables and counters shall be wiped down and the floor shall be wet vacuumed at the end of each shift.

- After instrumentation and equipment has been decontaminated, it will be passed to the clean area of CPD to be processed for sterilization.

Sterile Processing

Sterilization:

- Pre-vacuum steam sterilizers, operate at 270° F and above 30 PSI with an exposure time of 6 minutes.
- Packs that have been removed from sterilizers will not be put away until they are cool to the touch. Wet and/or hot packages will transfer bacteria and act as a wick.
- Sterrad sterilization utilizes hydrogen peroxide in gas form (forming free radicals when placed under specific temperature, time, and pressure conditions) to sterilize instrumentation. The cycle takes between 24 and 75 minutes and requires no aeration phase.

Quality assurance/improvement:

- Testing and documentation shall be performed daily, according to CPD’s policies/procedures as well as the manufacturer’s instructions.
A biological test (spore test/Geobacillus Stearothermophilus for steam and Sterrad) will be performed on each load of gear for steam and Sterrad. Testing will be performed with the first load of the day on Sterrad. Incubation of these tests are read as follows:

- 3 hours on steam claves in CPD and MOR sub-sterile areas
- 1 hour on steam claves in the MOR sub-sterile areas
- 48 hours on Sterrad

The steam clave is to be secured if a biological indication test fails. Medical Repair will be notified. Following the completion of repairs and three subsequent negative biologics the steam sterilizer may be brought back into service.

A vacuum test (Bowie Dick) will be performed on each pre-vacuum sterilizer and flash sterilizer as the first cycle of each day. An unsatisfactory result requires the medical repair technician on duty to be notified to check for problems. After completion of repairs, another vacuum test will be performed to ensure correction of the problem (along with the three consecutive negative biologics) prior to the sterilizer being used to sterilize gear.

Chemical testing will be performed once daily on steam sterilizers as part of the challenge pack (first pack of the day), in every flash load, and once a day with the biological test pack on the Sterrad. In addition, each piece of instrumentation placed in a steam or Sterrad sterilizer will contain its own external and internal chemical indicator.

Sterile commercially prepared items will not be re-sterilized except under unusual circumstances with proper recommendations from the manufacturer.

At no time will any dirty gear be allowed into the sterilization area of CPD.

Packaging, storage, and distribution:

- Items sterilized by the Central Processing Division will have an indefinite shelf life (event related sterility) as long as the integrity of the packaging is not compromised and environmental criteria have been maintained. No expiration date will be present.

- Package integrity is defined as:
  - A package is considered un-sterile if the wrapper has been torn, punctured, or is wet or moist (or has the appearance that it was wet and then dried), opened, mishandled, or damaged in any other way.
  - Packaged or wrapped items are not sterile if the tape is broken.
  - Peel pack pouches are not sterile if they are not sealed correctly or if they are excessively wrinkled.
  - Items with an external chemical indicator, which has not changed, are not sterile.
  - Closed container systems that do not have locks, filters, external indicators, or lids that do not fit properly are not sterile.
  - Items in a plastic dust protector, which is unsealed, are not sterile.
  - If the package has not been handled and stored properly, it is not sterile (see below for specific guidelines).

Procedure:

- Sterile items may be used as long as the integrity of the package is not compromised.
- A sterilizer load sticker will be placed on each package for recall purposes only. It will include the date the item was sterilized and also a load control number indicating the sterilizer used and the load number.
• All items will be properly wrapped and processed in such a manner as to provide an effective barrier to microorganisms and allow aseptic presentation upon opening.

• All items processed for sterilization will be wrapped in 2 ply Kimberly-Clark Kimguard® disposable sterilization wrap, paper/plastic peel-pouches, or placed in a closed container system.

• Certain items may be dust-covered to maintain the integrity of the package. Dust cover use will be determined by frequency of use, storage, and handling conditions.

• Medications or materials within a package that deteriorate over time will be dated with an expiration date.

• Commercially prepared items that do not have an expiration date from the manufacturer are sterile unless the package has been compromised. The loss of sterility is event-related, not time-related.

• It is important to ensure proper handling, transport, and storage of items in a manner that does not compromise the packaging of the product.

• Sterile items obtained from CPD should be covered for transport. Use of clean transport carts or plastic bags is required.

• Items should be handled with care and only as needed. Personnel should wash their hands prior to handling sterile items. Sterile items should not be carried under the arms or cradled in the arms. If the item is too heavy for transport, the item should be covered in plastic and transported on a clean cart. Items should be properly stored immediately after transport and remain stored until used for patient care.

• Items that have been dropped must be inspected for damage to the package. Unless the package is heat-sealed in impervious plastic and the seal is still intact, the package should be considered contaminated if it has been dropped.

• Storage spaces should not compromise the integrity of sterile packages in any way. All storage spaces must be cleaned on a weekly basis.

• Outside shipping cartons are not allowed in either a clean storage area or a sterile storage area and they should never be used as storage containers in these areas. These boxes are dirty from the shipping process and they may contain insects. In particular, corrugated cardboard boxes harbor dust and bacteria in the grooves and are sources of fungal contamination and bacterial spores.

Sterile Storage Area Requirements:
• Room temperature: Less than or equal to 75°F
• Room humidity: Less than or equal to 70%
• Air movement: Positive (out) air flow with a minimum of 4 (downdraft type) air exchanges per hour for clean/sterile storage areas.
• Traffic: Limited to those personnel who need to be there.
• Space: Closed shelves are the preferred method of storage. Open doors slowly and avoid crowding and stacking. If open shelves are used, they should be wire mesh or kept dust free. The shelves should keep sterile packages at least 8-10” from the floor, 18” from the ceiling or ceiling fixture, and 2” from the outside walls. The shelves should be kept away from sinks, windows, doors, and exposed pipes and vents. Ensure a barrier between the bottom shelf and the floor and that items on the top shelf are protected. Space between packages should be sufficient to avoid
compression of supplies. Particular attention should be paid to the storage of paper/plastic peel-pack pouches.

- All sterile packages must be rotated on a 1st in, 1st out basis.
- Some items will remain on storage shelves for varying lengths of time. Items should be evaluated as to the need to keep them sterile. If necessary, items may be placed in plastic dust covers at the request of the departments sending items to be processed.
- All packages must be inspected before using.
- A dating label must be applied to each package to be used only for recall purposes. This is not to be used as an expiration date.
- The user must inspect all packages before the package is opened. If the package is damaged, then item is not sterile and cannot be used. Always verify that the external indicator has been exposed to the sterilant.

CPD Environment

Routine cleaning:

- CPD will be cleaned at the change of each shift. This will include re-stocking vital supplies, sweeping the entire area, wet vacuuming as necessary, wiping down flat surfaces, and emptying all trash.
- CPD field days will be held. The senior technician on board will take charge and assign the various duties.
- Completely clean the sterilization room. The decontamination process begins at the highest level and progresses downward.
  - Clean ceiling and walls with sponge mop.
  - Clean lights and venting.
  - Wipe down all furniture and carts with appropriate disinfectant.
  - Remove all load stickers from the floor.
  - Buff and wet vacuum floor with disinfectant solution.
  - Restock area.
- Completely clean the pack room.
  - Clean ceiling and walls with sponge mop.
  - Clean lights and venting.
  - Wipe down all furniture and carts with appropriate disinfectant.
  - Remove all load stickers from the floor.
  - Buff and wet vacuum floor with disinfectant solution.
  - Restock area.
- Completely clean trash, linen, and receiving rooms.
  - Clean ceiling and walls with sponge mop.
  - Clean lights and venting.
  - Wipe down all furniture and carts with appropriate disinfectant.
  - Remove all load stickers from the floor.
  - Buff and wet vacuum floor with disinfectant solution.
  - Restock area.
- Completely clean clinical supply room.
  - Remove all carts from room.
• Clean ceiling and walls with sponge mop.
• Clean lights and venting.
• Buff and wet vacuum floor with disinfectant solution.

Autoclave sterilizers will be cleaned weekly during the weekend shifts. Sterilizers 1 and 2 will be secured Friday night to allow cooling prior to cleaning on Saturday. Sterilizers 3 and 4 will be secured Saturday night to allow for cooling prior to cleaning on Sunday. Cleaning will be performed in accordance with the cleaning solution's manufacturer's directions. Sterilizers are to be returned to service as soon as cleaning is completed.

Preventive maintenance:
• All equipment within the division is evaluated and routinely maintained under the Preventative Maintenance Program. The Facility’s Department maintains and performs repairs on all structural aspects of CPD.

Recall of Material Sterilized by CPD
• Biological spore tests are run for each steam sterilizers and Sterrad sterilizer.
• If a positive test should occur, all sterilized equipment from that load will be recalled and reprocessed by the CPD staff.
• The CPD Division Officer shall initiate the recall and CPD personnel will contact each area suspected of having materials from the failed load.
• The CPD Division Officer shall submit any follow-up reports required by the affected departments. This report will reflect final disposition of any suspected item. If any suspected items were used prior to recall, a list of patients and their physicians must be included. All individual areas are responsible to follow-up with patient’s physician. In addition, the Infection Control Department should be notified of these events when they occur.
Guidelines for Immediate Use (Flash) Sterilization

References
AORN Standards and Recommended Practices, 2011, Association for the Advancement of Medical Instrumentation

Policy
- Immediate Use (Flash) sterilization should be used only when time does not permit sterilization by the preferred wrapped procedure.
- The unwrapped method may be used in emergency situations for individual items (i.e., dropped instruments). Complete sets or trays of instruments may be immediate use sterilized/flashed if the following conditions are met:
  - There is an urgent need.
  - Proper decontamination, cleaning, inspection, and arrangement of instruments prior to sterilization.

Procedure
- All contaminated instruments to be immediate use sterilized/flashed will be manually decontaminated prior to placement in the steam sterilizer.
- Don protective gear (i.e., eye protection, gloves, apron if appropriate).
- Rinse items under cold water.
- Spray instrument with enzymatic solution.
- Clean items with scrub brush under water to avoid aerosolization. Inspect for cleanliness.
- Place items in immediate use/flash sterilization pan with chemical indicator. Metal or nonporous items are sterilized for 3 minutes at 270° F (135° C) in either the gravity or prevac cycle. Items with lumens or complex items require a 10 minute 270° F (135° C) gravity cycle or 4 minute 270° F (135° C) prevac cycle.
- If time permits, all instruments needed for another scheduled case should be taken to CPD for decontamination and returned to OR for immediate use sterilization/flashing. This will take approximately 1 hour. Notify CPD in advance for prompt service.
- Immediate Use (Flash) sterilization should not be used for implantable devices except in cases of emergency when no other option is available. In an emergency a rapid-action (1 hour blue top) biological indication will be run with the load. Following sterilization, the implant should be quarantined until the rapid-action biologic provides a negative result.

Documentation
- Documentation of cycle information and monitoring results will be maintained in a file to provide tracking of the flashed item(s) to the individual patient.
- Documentation allows every load of sterilized items used on a patient to be traced.
- Sterilization records should include information on each load, including:
• The item(s) processed;

• The patient receiving the item(s)

• The cycle parameters used (e.g., temperature, duration of cycle)

• The date and time the cycle is run

Revised: Mar 2006; 20 Mar 2011