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HEALTH INDUSTRY STANDARD

WS/T 855—2025

Standard for infection control in operating suites

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Preface

This is a recommended standard.

This standard is under the charge of the Hospital Infection Control Standard Professional Committee of the National Health Commission for technical review and consultation, the Medical Administration Service Guidance Center of the National Health Commission for consistency and format review, the Medical Administration Department of the National Health Commission for business management, and the Department of Legal Affairs for overall management.

The drafting organizations of this document are Peking University People's Hospital; Beijing Jishuitan Hospital, Capital Medical University; China-Japan Friendship Hospital; Ruijin Hospital, Shanghai Jiaotong University School of Medicine; Beijing Tiantan Hospital, Capital Medical University; Tongji Hospital Affiliated to Tongji Medical College of Huazhong University of Science & Technology; Beijing Friendship Hospital, Capital Medical University; Beijing Obstetrics and Gynecology Hospital; and West China Second University Hospital, Sichuan University.

The drafters of this document are WU Yinghong, CHEN Hui, SUN Yuhong, QIAN Qianjian, ZHANG Yuewei, ZHAO Tiyu, WANG Fei, YAN Qiuju, HUANG Chan, and LI Juan.

Standard for infection control in operating suites

Yinghong Wu[1], Hui Chen[2], Yuhong Sun[3], Qianjian Qian[4], Yuewei Zhang[5], Tiyu Zhao[6], Fei Wang[7], Qiuju Yan[8], Chan Huang[1], Juan Li[9]

(*1. Peking University People's Hospital; 2. Beijing Jishuitan Hospital, Capital Medical University; 3. China-Japan Friendship Hospital; 4. Ruijin Hospital, Shanghai Jiaotong University School of Medicine; 5. Beijing Tiantan Hospital, Capital Medical University; 6. Tongji Hospital Affiliated to Tongji Medical College of Huazhong University of Science & Technology; 7. Beijing Friendship Hospital, Capital Medical University; 8. Beijing Obstetrics and Gynecology Hospital; 9. West China Second University Hospital, Sichuan University*)

1 Scope of application

This standard specifies the requirements for nosocomial infection control in operating suites (rooms). It includes control principles, environment control, personnel management, operation management for aseptic techniques, surgical instrument management, equipment management, item management, usage management of prophylactic antimicrobials, medical waste management, and hygienic monitoring and investigation.

This standard applies to hospitals with operating suites. Other medical institutions performing surgeries may refer to and implement it.

2 Normative references

The following normative references contain provisions, which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the normative reference (including any amendments) referred to applies.

Hygienic standard for disinfection in hospitals (GB 15982)

Protective face mask for medical use (GB 19083)

General principle on disinfection for infectious focus (GB 19193)

Architectural technical code for hospital clean operating department (GB 50333)

Code for construction and acceptance of cleanroom (GB 50591)

Central sterile supply department (CSSD). Part 1: Management standard (WS 310.1)

Central sterile supply department (CSSD). Part 2: Standard for operating procedure of cleaning, disinfection, and sterilization (WS 310.2)

Central sterile supply department (CSSD). Part 3: Surveillance standard for cleaning, disinfection and sterilization (WS 310.3)

Specification of hand hygiene for healthcare workers (WS/T 313)

Regulation of disinfection technique in healthcare settings (WS/T 367)

Regulation for cleaning and disinfection technique of flexible endoscope (WS 507)

Standard for washing and disinfection technique of medical textiles in healthcare facilities (WS/T 508)

Standard for cleaning and disinfection management of environmental surface in healthcare facilities (WS/T 512)

Surgical mask (YY 0469)

Surgical drapes, gowns, and clean air suits for medical use — Part 1: General requirements (YY/T 0506.1)

3 Terms and definitions

The terms and definitions that apply to this document are as follows.

3.1 Operating suite

An independent functional area composed of an operating room and auxiliary room, used for centralized surgical operations on patients.

3.2 Operating room

A room where surgical operations are performed on patients.

3.2.1 General operating room

An operating room without an air purification

system, where indoor hygiene indicators comply with the normative reference GB 15982.

3.2.2 Clean operating room

An operating room that reduces the total amount of microbial particles and particulates in the surgical environment to an allowable level using air cleanliness technology.

3.2.3 Isolated operating room

A room for performing surgery on patients infected with prion diseases, Category A infectious diseases, Category B infectious diseases that are managed with Category A measures, gas gangrene, pathogens of unknown cause, airborne diseases, etc.

3.3 Restricted area

An area with strict restrictions on personnel and material flow to maintain high environmental hygiene and cleanliness in the surgical area. It includes an operating room, inner and outer corridors of the surgical area, a sterile storage room, a medicine room, an anesthesia preparation room, an equipment room (area), a scrub area (room), and other facilities.

3.4 Semi-restricted area

An area with restrictions on personnel and item flow to maintain certain environmental hygiene and cleanliness in the surgical area. It includes a surgical instrument room, a specimen holding room, a post-anesthesia care unit (PACU), and other facilities.

3.5 Non-restricted area

A work area without special cleanliness requirements, including office area, rest area, changing area, and patient waiting area (room).

3.6 Hand hygiene

A general term for hand washing, antiseptic hand rubbing, and surgical hand antisepsis performed by healthcare workers during occupational activities.

[Source: Item 3.1, WS/T 313—2019]

3.6.1 Hand washing

The process of healthcare workers rubbing and rinsing their hands with running water and liquid hand soap or bar soap to remove dirt, debris, and some microorganisms from the hand skin.

[Source: Item 3.2, WS/T 313—2019]

3.6.2 Antiseptic hand rubbing

The process of healthcare workers rubbing their hands with hand disinfectant to reduce transient microorganisms on the hands.

[Source: Item 3.3, WS/T 313—2019]

3.6.3 Surgical hand antisepsis

Before surgery, healthcare workers wash their hands using running water and liquid hand soap with a brush or by rubbing hands together, forearms up to the lower one-third of the upper arms, and then rub using surgical hand disinfectant, remove or kill transient microorganisms and reduce resident microorganisms on the hands, forearms up to the lower one-third of the upper arms.

[Source: Item 3.4, WS/T 313—2019]

3.7 Air cleanliness

The allowable number of aerosols greater than or equal to a specified size per unit volume of air in a clean environment.

3.8 Scrub attire

Special clothing that has been cleaned and disinfected, worn when performing surgical hand antisepsis before surgery.

3.9 Surgical gown

Sterile clothing worn by surgical personnel. Its performance requirements shall comply with the normative reference YY/T 0506.1.

3.10 Personal protective equipment, PPE

Special clothing or equipment that is used by healthcare workers to protect themselves from the risk of infection caused by exposure to patient blood, body fluids, or tissues. It includes gloves, masks, caps, goggles, face shields, waterproof aprons, isolation gowns, protective clothing, protective footwear, shoe covers, PPE with ventilation devices, etc.

3.11 Skin preparation

The process of cleaning, disinfecting, or using special tools to remove or trim hair in the operating field on the patient's skin before surgery.

3.12 Neutral zone

An area used for placing and passing sharp instruments during surgery, enabling contactless transfer of sharp instruments through this area.

3.13 Non-contact transfer

A method of passing and receiving sharp instruments during surgery through the neutral zone.

4 Control Principles

4.1 The construction of the operating suite shall be included in the hospital's construction planning and be made compatible with the hospital's service functions, construction scale, and development plans. Infection control in the operating suite shall be incorporated into medical quality management to ensure medical safety.

4.2 The architectural layout of the operating suite in the hospital shall comply with relevant national regulations and meet the requirements for environmental pollution control.

4.3 Hospitals shall, based on diagnostic and treatment needs, set up separate areas for outpatient surgery, day surgery, and inpatient surgery, with centralized management.

4.4 The operating suite shall have an isolated operating room; the isolated operating room in a clean operating suite is typically negative-pressured.

4.5 Hospitals shall formulate general systems for the prevention and control of nosocomial infections in the operating suite, specifically following the requirements in Appendix A.

4.6 A comprehensive infection control risk assessment shall be conducted for newly introduced surgical techniques, newly used instruments, equipment, consumables, etc.

4.7 The surgical area and order of surgeries should be arranged reasonably based on the surgical infection risk level. When surgeries with different incision classes are performed in the same operating room, they shall be scheduled in order from clean to contaminated.

4.8 After each surgery, the operating room shall undergo corresponding treatment; after all surgeries for the day, terminal disinfection shall be performed, complying with the requirements in Appendix B.

4.9 Before performing surgery on patients with concurrent infectious diseases, special pathogen infections, or patients confirmed to carry multidrug-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA), the clinical department shall notify the operating suite to prepare for appropriate isolation.

4.10 Surgeries on patients infected with prion diseases, Category A infectious diseases, Category B infectious diseases managed with Category A measures, gas gangrene, pathogens of unknown cause, and airborne diseases shall be conducted in isolated operating rooms.

4.11 The personnel participating in surgery shall choose appropriate PPE based on the potential infection exposure risks of the surgery.

4.12 Items directly contacting the surgical patient shall be used, cleaned, disinfected, or sterilized for one patient only.

4.13 The disinfection and sterilization processing of various surgical instruments, equipment accessories, and other items after use shall be centrally handled by the Central Sterile Supply Department (CSSD) to achieve homogeneous management.

5 Environment Control

5.1 Architectural and layout requirements

5.1.1 The operating suite shall be an independent zone. Access routes shall comply with the management principles of separating clean and contaminated areas and separating healthcare workers and patients.

5.1.3 Each operating room shall have one operating table only. The minimum net usable area shall not be less than 30 m^2, and the clear height shall be 2.7 m to 3.0 m.

5.1.4 Hospitals shall have preoperative preparation rooms and post-anesthesia care units (PACU) in the operating suite, if possible.

5.1.5 The operating room shall have basic equipment and items to maintain the patient's body temperature during the perioperative period. Computer terminals shall use touchscreens.

5.1.6 Surgical hand antisepsis facilities shall comply with the normative reference WS/T 313 and the following:

a) One scrub room (area) shall be established separately for every 2~4 operating rooms. Scrub sinks shall be near the operating rooms, have a splash-proof function, and an access door for maintenance;

b) The height shall facilitate cleaning of hands and arms. Hand-washing liquid, surgical hand disinfectant, hand-drying items, mirrors, clocks, and other facilities shall be installed at appropriate positions.

5.1.7 Waste disposal and holding rooms shall meet the needs for processing contaminated utensils such as drainage bottles and waste bins, and temporarily storing large amounts of medical waste and dressings after surgery.

5.1.8 Architectural requirements for general operating rooms are as follows:

a) Walls shall be smooth, made of moisture-proof, mildew-proof, dust-free, non-generating, corrosion-resistant, and easy-to-clean materials;

b) Walls and floors shall be an integral whole. The inside corner where the skirting meets the floor shall be a rounded corner with $R \geqslant 30$ mm; inside corners where walls meet shall be small rounded corners;

c) Floors shall be level, waterproof, made of wear-resistant, corrosion-resistant, easy-to-clean, light-colored materials. Floor drains shall not be installed in the operating room;

d) Suspended ceilings shall not be made of multi-seam plasterboard;

e) Doors and windows shall have good airtightness.

5.1.9 Architectural facilities in the clean operating room shall comply with the normative reference GB 50333.

5.1.10 Isolated operating rooms shall have their own zone with independent entrances/exits, independent air conditioning or purification systems, and an anteroom.

5.1.11 Air disinfection devices shall be installed as needed when effective ventilation cannot be achieved in an isolated operating room.

5.1.12 During partial renovation or expansion of the operating suite, an infection control risk assessment shall be conducted, and full physical separation between the renovated area and other areas of the operating suite in use shall be ensured.

5.2 Cleaning and disinfection of environmental surfaces

5.2.1 The cleaning and disinfection principles in the normative reference WS/T 512 shall be followed, including cleaning before disinfection, wet cleaning, and unitized cleaning and disinfection.

5.2.2 Before each day's work, the environment and surfaces inside and outside the surgical area, transport tools, etc., shall be cleaned and disinfected. Clean and wipe in the order from top to bottom, inside to outside; appropriate disinfectants shall be used if necessary; and complete 30 minutes before use.

5.2.3 The operating table and environmental surfaces within at least 1 m to 1.5 m around it shall be cleaned and disinfected after each surgery.

5.2.4 Visible or suspected contamination shall be cleaned and disinfected promptly if it occurs on surfaces around the operating table, floors, or equipment.

5.2.5 After all surgeries for the day, terminal cleaning and disinfection of the operating room and surfaces shall be performed. The sequence shall follow the principle from less contaminated to more contaminated areas. Appropriate disinfection shall be performed after cleaning and wiping the environment and surfaces such as shadowless lamps, IV poles, anesthesia machines, instrument carts, operating beds, and floors, based on the degree of contamination.

5.2.6 In addition to the daily terminal disinfection, a comprehensive and thorough cleaning and disinfection of the operating suite shall be performed and recorded weekly. General requirements for cleaning and disinfection of the operating suite comply with Appendix B.

5.2.7 Microfiber fabric shall be applied in cleaning and disinfection supplies. Different areas shall use separate supplies with clear identification. They shall be washed, disinfected, and stored dry after use.

5.2.8 During surgery, the surfaces shall be cleaned promptly and disinfected if they are contaminated with blood or body fluids.

5.2.9 After surgery on patients infected with prion diseases, Category A infectious diseases, Category B

infectious diseases managed with Category A measures, gas gangrene, or pathogens of unknown cause, terminal disinfection shall be performed according to the normative references GB 19193 and WS/T 367.

5.2.10 For negative-pressure operating rooms where high infection risk surgeries are performed, if the purification control system is a 100% fresh air and 100% exhaust direct current system, the high-efficiency filter at the exhaust outlet shall be replaced after surgery; if it is a purification system with partial recirculated air (i.e., partial return air), the medium-efficiency filter or high-efficiency filter at the upper exhaust outlet, the high-efficiency filter at the lower exhaust outlet, and the medium-efficiency filter at the return air outlet shall be replaced after surgery. Staff shall have PPE when replacing filters.

5.3 Air pollution control

5.3.1 The doors (windows) of the operating room shall remain closed during surgery.

5.3.2 For general operating rooms with external windows, natural ventilation can be performed after surgeries each day, followed by surface cleaning and disinfection. Legally effective air disinfectors can also be used. For general operating rooms with air conditioning systems, effective measures to prevent duct contamination shall be taken for fresh air inlets and return air inlets.

5.3.3 Air purification systems for different functional areas in a clean operating suite shall be set up independently.

5.3.4 The installation of return air inlet filtration devices for the air purification system in a clean operating room shall follow the normative reference GB 50333.

5.3.5 The terminal air supply devices of the air purification system shall achieve zero leakage.

5.3.6 Non-barrier type purification devices shall not be used as terminal air supply devices in air purification systems.

5.3.7 Negative-pressure operating rooms should have devices specifically for controlling, collecting, filtering, and discharging aerosols, contaminated medical waste liquids, and surgical smoke.

5.3.8 Daily management of the air cleanliness system in clean operating rooms shall comply with the following requirements:

a) Professional technical personnel shall be in charge of daily management and maintenance of the air cleanliness system in clean operating rooms;

b) Ordinary air supply outlets of air handling units shall be inspected and cleaned monthly; when the surface of the terminal air supply outlet is soiled, it shall be replaced promptly;

c) When the pressure differential indicated by the test port or micromanometer reaches the set parameter requiring replacement, filters shall be replaced;

d) Coarse filter screens shall be cleaned at least once a week, with the cleaning effect being no visible dust or debris;

e) The static pressure differential, temperature, and relative humidity of the clean operating room shall be recorded daily before the first surgery;

f) The air cleanliness device shall be turned on normally 30 minutes before the first surgery each day, and environmental parameters shall meet the normative reference GB 50333;

g) Surface cleaning and disinfection shall be performed between surgeries as required in section 5.2.3;

h) The air cleanliness system shall continue running for 30 minutes after all surgeries for the day and after comprehensive cleaning and disinfection;

i) Air cleanliness devices shall be used within their expiry date, maintained according to the manufacturer's instructions, and replaced regularly or promptly if contaminated;

j) The requirements for dynamic control of environmental pollution in negative-pressure operating rooms follow Appendix C.

6 Personnel Management

6.1 General requirements

6.1.1 Staffing in the operating suite shall comply

with relevant national regulations.

6.1.2 Healthcare workers in the operating suite, clinical medical personnel participating in surgery, onlookers/trainees, and support staff shall all receive training or assessment on nosocomial infection prevention and control knowledge.

6.1.3 Persons unrelated to surgery or personnel from medical device manufacturers shall not participate in surgery and be restricted from entry and exit of the operating suite arbitrarily; non-surgical personnel entering restricted areas shall move within the restricted scope according to the personnel flow route.

6.1.4 The number of people in the operating room and the frequency of entry/exit shall be limited while meeting basic surgical needs. For clean operating rooms, the number of people in Grade Ⅰ clean operating rooms should not exceed 14, the number of people in Grade Ⅱ clean operating rooms should not exceed 12, and the number of people in Grade Ⅲ and Grade Ⅳ clean operating rooms should not exceed 10. Requirements for the general operating room shall be referred to in this context.

6.1.5 Healthcare workers in the infectious phase of acute upper respiratory infections, infectious diarrhea, skin boils, exudative skin lesions, etc., shall not enter the restricted areas of the operating suite.

6.1.6 Personnel participating in surgery shall trim their nails short and maintain personal hygiene before performing surgery; personal items such as mobile phones and computers shall not be brought into the operating room.

6.1.7 Each circulating nurse shall only be responsible for assisting in one surgery at a time.

6.1.8 Management requirements for onlookers are as follows:

a) Onlookers and personnel who need to enter a restricted area temporarily shall enter designated locations under the guidance of reception personnel after obtaining approval from the operating suite manager, and shall not enter other operating rooms arbitrarily;

b) Each operating room shall not have more than three onlookers. During viewing, a distance of more than 30 cm from the surgeon shall be maintained, and surgistool height shall not exceed 50 cm.

6.2 Attire requirements

6.2.1 When entering the operating suite, staff shall first perform hand hygiene, then change into scrub attire, shoes, caps, and surgical masks dedicated for the operating suite; if reusable cloth caps are used, they shall be cleaned and disinfected daily.

6.2.2 Personnel participating in surgery shall not wear rings, watches, bracelets, earrings, beaded necklaces, or other jewelry, and shall not have false eyelashes or artificial nails.

6.2.3 Scrub shirt tops shall be tucked into pants. Surgical caps shall cover all hair and the hairline. The mouth and nose shall be completely covered with masks. Inner clothing shall not be exposed outside the scrub attire or onlooking attire (e.g., collars, sleeves, pant legs).

6.2.4 Dedicated surgical shoes shall be worn, cleaned for one person only, and should not be changed into a second time.

6.2.5 Surgical gowns, scrub attire, and dedicated surgical shoes shall be worn within the operating suite. When temporarily going out, one shall change into outdoor shoes and wear outdoor clothing.

6.2.6 Scrub attire and surgical gown should be comfortable, breathable, fluid-resistant, of moderate thickness, with fibers not easily shedding, and anti-static; they shall be cleaned, disinfected, or sterilized promptly after use.

6.2.7 Dedicated surgical shoes shall cover the instep and be kept clean and dry; they shall be cleaned or disinfected daily and changed promptly when contaminated.

6.3 Occupational safety protection for healthcare workers

6.3.1 The operating suite shall have PPE that prevents penetration and splashing of blood and body fluids, such as fluid-resistant surgical apparel, goggles, face shields, and full-cover surgical caps, complying with relevant national standards.

6.3.2 Surgical masks used by surgical personnel shall comply with the normative reference YY 0469. When

performing surgery on patients with airborne diseases, or when aerosol or large amounts of smoke may be generated during surgery, a disposable protective face mask for medical use complying with the normative reference GB 19083 or a full-face respirator shall be worn.

6.3.3 Healthcare workers shall have regular health check-ups and necessary immunizations.

6.3.4 If staff are contaminated by blood/body fluids or have contact with infectious disease patients during surgery, they should shower and change clothes before participating in the next surgery.

6.3.5 Healthcare workers shall be proficient in various puncture methods and the operation of sharp instruments, comply with operating procedures, and prevent injuring themselves or others. Precautions for sharps operations shall include:

a) Non-contact transfer when passing sharps;
b) Do not recap needles with two hands after use; if recapping is needed, use a tool or single-hand technique;
c) Assemble or disassemble sharps using tools, not bare hands;
d) During surgeries with high risk of injury exposure, such as orthopedics, wear double gloves or special protective gloves, and protective goggles;
e) Each operating room shall be equipped with sharps containers or blade retrievers;
f) The operating suite should use surgical instruments, injection devices, safety suture devices, and other safety assistive tools with safety protection features;
g) Before and after installing powered equipment such as electric drills and saws, turn off the power. When passing equipment, do not point the sharp end towards others;
h) Disassemble sharp items such as saw blades, Kirschner wires, and bone drills within the neutral zone.

6.4 Skin preparation for surgical patients

6.4.1 Patients shall bathe, clean the surgical site, and change into clean patient apparels preoperatively.

6.4.2 Skin preparation at the surgical site should be performed on the day of surgery, shortly before the procedure, in the ward or in the patient preparation area (room) outside the restricted area of the operating suite.

6.4.3 If hair interferes with the operation at the surgical site, hair shall be removed by a method that does not damage the skin.

6.4.4 For emergency patients or those with open wounds, it should first remove stains, blood, exudate, remove contaminated clothing, and cover the wound before entering the restricted area of the operating suite.

7 Operation Management for Aseptic Techniques

7.1 Strictly implement the principles of aseptic techniques and the standards for surgical hand antisepsis.

7.2 The sterile area includes but is not limited to: the instrument table and the area above the operating table after sterile drapes are placed, the front of the surgeon’s gown (above the waist, below the shoulders, and between the midaxillary lines). The surgical gown and sterile drapes shall be replaced immediately if suspected contamination occurs.

7.3 Requirements for sterile draping of the instrument table and surgical drapes are as follows

a) Reusable surgical instruments and sterile dressing packs shall be inspected according to the normative reference WS 310.3. Wet packs and those with suspected contamination, damaged packaging, or packs failing sterilization shall not be used and shall be reprocessed according to the normative references WS 310.1 and WS 310.2;
b) The sterile instrument table should be draped with a single-layer fluid-resistant sterile drape that meets the performance requirements of the normative reference YY/T 0506.1;
c) If cotton drapes are used, four or more layers shall be placed; the draped instrument table shall ensure the sterile drape overhangs by more than 30 cm on all sides and is more than 20 cm from the floor. In clean operating rooms, the lower edge of the sterile drape

shall be above the return air inlet. Sterile drapes without fluid-resistant property shall be considered contaminated when damp;

d) Draping the sterile instrument table shall be done as close to the surgery start time as possible. Sterile items shall be opened closest to their time of use. Items unused for over 4 hours shall be considered contaminated and replaced;

e) Surgical drapes shall be placed by healthcare workers who have completed surgical hand antisepsis.

7.4 Operation management requirements are as follows

a) Skin disinfection of the surgical area shall be centered on the incision. For clean incisions, disinfect from the center outward, covering an area of more than 15 cm. For contaminated incisions, disinfect from the periphery inward;

b) The one donning a sterile surgical gown shall not leave the operating room arbitrarily. If a gown change is needed during surgery, remove the gown first, then the gloves. In principle, surgical hand antisepsis shall be performed before donning a sterile surgical gown and sterile gloves;

c) Gloves shall be changed promptly, followed by antiseptic hand rubbing if they are torn or suspected torn during surgery,;

d) One item shall be replaced promptly if the sterility of it is in doubt during surgery; surgical instruments, devices, and medications shall be used for one patient only. Unused sterile holding forceps and containers unused for over 4 hours shall be considered contaminated and replaced;

e) Instruments and items in the surgical field that have contacted hollow viscera, contacting with the outside or other contaminated areas, shall be considered contaminated and placed separately;

f) Keep the instrument table dry during surgery. When passing sterile instruments, avoid the surgical field, do not pass from behind, and the surgeon shall not retrieve the instruments themselves;

g) Anesthesia items (suction catheters, laryngoscope blades, etc.) and medications used during surgery shall be placed within a sterile treatment basin (towel).

8 Surgical Instrument Management

8.1 Surgical instruments shall be managed according to the following classifications

a) Reusable surgical instruments (including loaner instruments) shall be cleaned, disinfected, and sterilized following the normative references WS 310.1, WS 310.2, and WS 310.3. Sterile instruments shall be stored in the sterile storage room within the restricted area; non-sterile instruments shall be stored in areas outside the restricted area;

b) Powered surgical instruments shall undergo performance testing annually and be cleaned, disinfected, or sterilized according to the instruction;

c) Passive microsurgical instruments and precision instruments shall have specific management procedures:

1) Microsurgical instruments shall be cleaned, disinfected, and sterilized according to the usage requirements of different specialty groups and instrument characteristics;

2) Precision instruments and heat-sensitive surgical instruments shall be protected after use and not mixed with ordinary instruments. Their cleaning and disinfection shall refer to the manufacturer's instructions or manual guide and comply with relevant national standards.

8.2 The rapid sterilization cycle of emergency backup sterilizers in the operating suite shall not be used as a routine sterilization method for surgical instruments; the use and monitoring of sterilizers shall be incorporated into quality management, and its information shall be traceable.

8.3 The operating suite shall establish reasonable workflows and job responsibilities for instrument

pre-processing, handling, handover, and storage in full consideration of factors such as patient safety, work efficiency, workload, staffing, and instrument characteristics with the CSSD.

9 Equipment Management

9.1 Cleaning, disinfection, and sterilization management systems and operational procedures for equipment shall be formulated considering the characteristics of the operating suite.

9.2 Cleaning, disinfection, and sterilization methods for equipment used in the operating suite shall follow the product instructions.

9.3 New equipment shall have external packaging removed and be thoroughly cleaned before entering the operating suite. Routinely used equipment shall be cleaned and disinfected after each use. Cleaning and disinfection of equipment comply with Appendix D.

9.4 When placing and using surgical equipment in the operating room, do not block the return air inlet. After use, the equipment surface and cords shall be cleaned, wiped, and disinfected if necessary.

9.5 Equipment such as microscopes or C-arms shall be covered with a sterile cover when they cross the sterile field during surgery.

9.6 Cleaning and disinfection of equipment, tubing, and accessories directly contacting the patient shall follow the normative reference WS 310.2.

9.7 All equipment and tracks in the operating suite shall be cleaned and wiped weekly.

10 Item Management

10.1 The operating suite shall manage all used items according to nosocomial infection prevention and control principles.

10.2 Sterile items shall be stored in the restricted area of the operating suite. Storage shelf life shall comply with the normative reference WS 310.2. Sterile and non-sterile items shall be placed in separate cabinets or zones, arranged and used in order of disinfection/sterilization expiry date. Outer packaging of single-use items shall be removed outside the restricted area.

10.3 Sterile items shall be inspected for expiry date by designated personnel. Sterile items exceeding the expiry date shall be reprocessed according to the normative reference WS 310.2.

10.4 Single-use sterile items (including implants) shall be for single use only.

10.5 Sterile items shall be used for one procedure only and shall not be used across procedures.

10.6 Cleaning, disinfection, and sterilization of reusable items shall comply with the normative references WS 310.1, WS 310.2, and WS 310.3.

10.7 Reusable textile items shall be collected in leak-proof laundry bags for subsequent processing after use. Specifics comply with the normative reference WS/T 508.

10.8 The operating suite shall use disinfection products in a standardized manner, and usage management shall comply with the normative reference WS/T 367.

10.9 Disinfectants shall be managed by designated personnel, stored separately in suitable environments from other medications.

10.10 Items not directly contacting patients shall be cleaned and disinfected daily for single use.

10.11 Cleaning and disinfection of highly critical items such as anesthesia laryngoscopes shall refer to methods provided by the manufacturer to achieve high-level disinfection or sterilization.

10.12 Cleaning and disinfection of fiberoptic bronchoscopy and esophagus endoscopic ultrasonography shall follow the normative reference WS 507.

10.13 Surgical lead aprons shall be handled promptly if visibly contaminated and be comprehensively cleaned and disinfected weekly.

11 Usage Management of Prophylactic Antimicrobials

The management of antimicrobial use for surgical patients preoperatively or during surgery shall follow the latest documents, such as the *Administrative Measures for Clinical Application of Antimicrobial Agents* and *Guidelines for Clinical Application of Antimicrobial Agents*, ensuring standardized and rational use.

12 Medical Waste Management

12.1 Medical waste shall be classified and collected following relevant national regulations for medical waste management.

12.2 Medical waste shall be transported via dedicated passages or other enclosed approaches.

12.3 Pathological waste shall be collected in leak-proof medical waste bags and labeled as required.

12.4 Hospitals with centralized sewage treatment systems can discharge liquid waste directly; hospitals without centralized systems shall treat it according to the normative reference GB 19193.

12.5 Medical waste liquids generated during surgery should be collected using closed negative-pressure processing devices with pre-filled disinfectant. The collection bags already used shall not be cut or have their integrity compromised; a solidifying agent should be added to the bag after surgery, and it should be treated as infectious waste.

13 Hygienic Monitoring and Investigation

13.1 Environmental monitoring

13.1.1 Routine monitoring

13.1.1.1 Routine monitoring of the general operating room

13.1.1.1.1 Designated personnel shall monitor and record the temperature and relative humidity of the operating room daily in the morning.

13.1.1.1.2 Designated personnel shall inspect the cleanness of the operating room, auxiliary room, and inner corridor, including the floors, countertops, and walls, before surgery (including between consecutive surgeries).

13.1.1.1.3 Designated personnel shall monitor and record the cleanliness status of the air conditioning unit supply and return air inlets weekly.

13.1.1.1.4 Conduct sampling for air hygiene effectiveness on 25% of operating rooms quarterly, ensuring each room is monitored at least once per year. Monitor more frequently if any issue arises. The monitoring method follows the normative reference WS/T 367.

13.1.1.1.5 Periodically monitor the disinfection effectiveness of equipment based on its usage cycle and frequency. Monitor promptly if a surgical infection is suspected to be related to the environment.

13.1.1.2 Routine monitoring of the clean operating room

13.1.1.2.1 After construction completion, the clean operating room shall undergo project acceptance according to the normative reference GB 50333.

13.1.1.2.2 In addition to routine monitoring, a comprehensive performance evaluation of environmental indicators for the air cleanliness system in the clean operating suite shall be conducted at least every 1~2 years, with a test report provided.

13.1.1.2.3 Filter leakage and frame sealing shall be tested according to the normative reference GB 50591 during comprehensive performance testing.

13.1.1.2.4 Monitoring of hygienic indicators for the air purification system shall be conducted after surface cleaning and disinfection. Chemical disinfection of indoor air shall not be performed.

13.1.1.2.5 Monitor airborne microbe or settling microbe in the operating suite periodically. Complete testing for all rooms within one year. Testing standards refer to the normative reference GB 50333.

13.1.1.2.6 Designated personnel shall inspect and record temperature, relative humidity, and static pressure differential in the operating room daily in the morning.

13.1.1.2.7 Daily before surgery (including between consecutive surgeries), designated personnel shall inspect whether the operating room (including auxiliary room and clean corridor) is clean and whether items and equipment are orderly.

13.1.1.2.8 Designated personnel shall monitor and record the cleanliness of the return air inlet grilles, screens, and inner surfaces of ducts of the air purification devices in the operating suite weekly.

13.1.1.2.9 Inspect the cleanliness of the supply and return air inlets of local air purification devices in non-clean areas monthly.

13.1.2 Special monitoring

13.1.2.1 Special monitoring of the general operating room

13.1.2.1.1 Air monitoring shall be performed ac-

cording to the normative reference GB 15982 if postoperative infection is suspected to be related to the operating suite environment.

13.1.2.1.2 After maintenance or replacement of air disinfection devices or air-conditioning, static airborne bacterial count monitoring shall be performed according to the normative reference GB 15982.

13.1.2.2 Special monitoring of the clean operating room

13.1.2.2.1 If postoperative patient infection is suspected to be related to the operating suite environment, dynamic airborne bacterial count monitoring can be performed using the airborne microbe impactor method or the sedimentation method. Dynamic airborne microbe impactor sampling for total bacterial count shall be done preoperatively, intraoperatively, and postoperatively, as detailed in Appendix E.

13.1.2.2.2 For a newly built clean operating room or after equipment replacement/maintenance, the items such as air cleanliness and sealing shall be tested according to the normative reference GB 50333.

13.2 Environmental surface monitoring

Surfaces in the operating suite shall be monitored according to the normative reference GB 15982 if postoperative infection is suspected to be related to the operating suite environment.

13.3 Healthcare worker hand hygiene monitoring

13.3.1 Sampling of surgical hand antisepsis effectiveness among healthcare workers in the operating suite shall be conducted quarterly.

13.3.2 Monitoring methods shall be performed according to the normative reference WS/T 313.

Appendix A

（Normative）

General Systems for Prevention of Nosocomial Infection in Operating Suite

A. 1 Nosocomial infection prevention and control management system in the operating suite.

A.2 Aseptic technique operation system in the operating suite.

A.3 Hand hygiene system for surgical personnel.

A. 4 Basic knowledge training system on infection prevention and control for surgical personnel.

A.5 Infection risk assessment system related to surgical operations.

A. 6 Systems related to nosocomial infection prevention and control measures in the operating suite, including but not limited to: personnel management, occupational safety, cleaning, disinfection and isolation, anesthesia-related infection control, equipment management, loaner instrument management, management of infection surgeries, daily cleaning management, environmental cleaning and disinfection effectiveness monitoring, surgical instrument management, reusable instrument handover system, surgical dressing management, patient transfer, sterile item management, single-use item management, pathological specimen submission, medical waste management, etc.

A.7 Management system for the clean system, as well as daily monitoring and recording system for filter resistance and air conditioner condensate pan cleanliness of air purification equipment.

Appendix B

（Normative）

General Requirements for Cleaning and Disinfection of Operating Suite

B.1 The general requirements for cleaning and disinfection of the operating suite are shown in Table B.1.

Appendix C

（Normative）

Requirements for Dynamic Control of Environmental Pollution in Negative Pressure Operating Room

C.1 Air purification requirements for negative pressure operating room after surgery:

a) Disinfection of floors, various utensils, and equipment surfaces in the negative pressure operating room shall be performed before each startup and after surgery. The purifica-

Table B.1 General Requirements for Cleaning and Disinfection of Operating Suite

Item	30 minutes Before Surgery	Between Surgeries	Daily	Weekly
Floors (surgical area, exposed area)[a]	√	√	√	√
All floors			√	√
Inner/outer corridors	√		√	√
Surfaces (surgical area, exposed area)	√	√	√	√
All parts of operating bed	√	√	√	√
Surgistools (surface and legs)	√		√	√
Various carts: instrument carts, equipment carts, waste carts, etc.	√		√	√
Operating room walls, ceiling, glass, IV tracks				√
Shadowless lamp	√		√	√
Shadowless lamp arm, pendant columns				√
Central suction (suction tube connecting wall to drainage bottle)		√	√	√
Mobile suction (tube between bottles)			√	
Return air inlet grilles			√	√
Fresh air inlet and filter screens				√
Inside single-use item cabinets, medicine cabinets				√
Inside warming cabinets, refrigerators			√	√
Positioning pads, radiation protection items		√	√	√
All equipment in operating room: electrosurgical units, bipolar forceps, microscope, anesthesia machine, monitor, cardiopulmonary bypass machine, ultrasound, equipment cords and connections, etc.	√	√	√	√
Patient transport carts			√	√

Note 1: Items requiring processing include, but are not limited to, the above. The above suggested frequencies are for normal conditions; clean or disinfect promptly if contamination or other situations occur.

Note 2: [a] Floor cleaning and disinfection shall be performed no less than three times daily.

tion system shall run continuously until 30 minutes after cleaning and disinfection are completed; then consecutive surgeries for the same pathogen infection can be performed;

b) When positive/negative pressure conversion is conducted, indoor environment and air disinfection shall comply with the normative reference GB 15982;

c) Exhaust fan unit: After special infection surgery, if the exhaust fan unit is confirmed contaminated, first treat the outer surface of the exhaust (return) air inlet with an effective disinfectant, then replace the high-efficiency filter.

C.2 Safe, conveniently removable filter units should be selected. Coarse air filters should be replaced every 1~2 months; medium and high-medium efficiency filters every 3~6 months; sub-high efficiency filters every 12 months or more; high-efficiency filters every 36 months or more.

Appendix D

（Normative）

Cleaning and Disinfection of Equipment in Operating Suite

D.1 Cleaning and Disinfection of Anesthesia Machine

D.1.1 After use, its main unit surface shall be cleaned and wiped.

D.1.2 Accessories such as anesthesia masks, tubing, connectors, humidifiers, and breathing bags shall be cleaned and disinfected by the CSSD.

D.2 Cleaning and Disinfection of Surgical Power Tool

D.2.1 After use, its main unit surface and accessories, such as foot pedals, shall be cleaned and wiped.

D.2.2 After use, its mechanical parts without circuits shall be disassembled into the smallest unit and removed of blood stains. Parts with circuits shall be cleaned and wiped, then cleaned, disinfected,

and sterilized together with related accessories by the CSSD.

Appendix E

（Informative）

Air Quality Monitoring in Clean Operating Room

E. 1 Schematic Diagram of Air Quality Monitoring Sampling Points

Dynamic airborne microbe impactor sampling for total bacterial count shall be conducted preoperatively, intraoperatively, and postoperatively. The sampling points shall be 10 cm from the operating bed, as shown in Figure E.1.

E.2 Indicators for Dynamic Control of Environmental Pollution

The indicators for dynamic control of environmental pollution are shown in Table E.1.

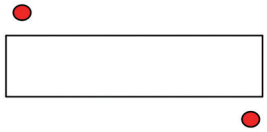

Figure E.1 Schematic Diagram of Air Quality Monitoring Sampling Points

Table E.1 Indicators for Dynamic Control of Environmental Pollution

Clean Room Level	Static Pressure Differential (Pa)	Dynamic Airborne Bacterial Count		Relative Humidity in Operating Suite	
	Clean pressure differential with adjacent room (Pa)	Settle plate at return air inlet (cfu per 90 mm diameter petri dish per 0. 5 h)	Airborne microbe impactor sampling (cfu/m^3)	Summer	Winter
Ⅰ	≥5	≤5	≤30	Events of 24 consecutive hours with relative humidity >60% shall not occur more than twice.	Events of 24 consecutive hours with relative humidity < 30% shall not occur more than twice.
Ⅱ	≥5	≤8	≤150		
Ⅲ	≥5	≤10	≤450		
Ⅳ	≥5	≤12	≤500		
Clean area to non-clean area	≥10				