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Regulation of disinfection technique in healthcare settings

医疗机构消毒技术规范

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was formulated in accordance with the Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases.

This standard was proposed by the Hospital Infection Control Standard Professional Committee of the Ministry of Health.

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Regulation of disinfection technique in healthcare settings

1 Scope

This standard specifies the management requirements for disinfection of medical institutions; the basic principles of disinfection and sterilization; washing and cleaning, disinfection and sterilization methods; cleaning, disinfection and sterilization effect monitoring, etc.

This standard applies to all types of medical institutions of all levels and all types.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this Standard.

GB/T 16886.7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

GB 19258 Ultraviolet germicidal lamp

GB/T 19633 Packaging for terminally sterilized medical devices

GB 50333 Architectural technical code for hospital clean operating department

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

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

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

WS/T 311 Technique standard for isolation in hospitals

WS/T 313 Standard for hand hygiene for healthcare workers in healthcare settings

YY/T 0506.1 Surgical drapes gowns and clean air suits for patient clinical staff and equipment - Part 1: General requirements for manufacturers processors and products

YY/T 0698.2 Packaging materials for terminal sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

YY/T 0698.4 Packaging materials for terminal sterilized medical devices - Part 4: Paper bags - Requirements and test methods

YY/T 0698.5 Packaging materials for terminal sterilized medical devices - Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction - Requirements and test methods

YY/T 0698.8 Packaging materials for terminal sterilized medical devices - Part 8: Reusable sterilization containers for steam sterilizers - Requirements and test methods

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Cleaning

It refers to the process of removing the organic matter, inorganic matter and visible pollutants from the surface of an object.

3.2

Washing

It refers to the whole process of removing the containments from the treatment instrument, appliance, and items, including washing, cleaning, rinsing and final rinsing.

3.3

Detergent

3.15

Non-critical items

It refers to the items contacting with the complete skin BUT not contacting with mucosa, such as stethoscope, sphygmomanometer cuff; bed fence, bed and bedside cabinet, bedding; wall, ground; spittoon (cup) and toilet.

3.16

Sterilization level

It refers to the sterility assurance level which is reached by killing all microorganisms including bacterial spores. Methods to achieve sterilization levels normally include such physical sterilization methods as heat sterilization and radiation sterilization AND the sterilization methods of using such chemical sterilizers as ethylene oxide, hydrogen peroxide, formaldehyde, glutaraldehyde, peracetic acid and so on to conduct sterilization at the specified conditions with appropriate concentration and effective time of action.

3.17

High level disinfection

It refers to killing of all bacterial propagules including mycobacteria, viruses, fungi and their spores, and the vast majority of bacterial spores. The normally used methods to reach to high level disinfection include using the chemical disinfectant such as chlorine preparations, chlorine dioxide, o-phthalaldehyde, peracetic acid, hydrogen peroxide, ozone, iodine tincture and so on, which can achieve sterilization effects, to conduct disinfection at the specified conditions with appropriate concentration and effective time of action.

3.18

Middle level disinfection

It refers to the killing of a variety of pathogenic microorganisms other than bacterial spores, including mycobacteria. The methods normally used to achieve to the middle level disinfection include using of iodine disinfectants (iodophor, chlorhexidine iodine, etc.), alcohols and chlorhexidine compound, compound of alcohols and quaternary ammonium compounds, phenols and other disinfectants, to conduct disinfection at the specified conditions with appropriate concentration and effective time of action.

aggregate on a solid culture medium, which is used to express the number of viable bacteria.

4 Management requirements

4.1 The medical institutions shall, in accordance with the requirements of this regulation AND combining with the actual situation of the unit, establish the scientific and practical disinfection & sterilization system and standard operating procedures, AND make them implemented.

4.2 The medical institutions shall enhance the training of the medical staff and disinfection & sterilization staff. Training shall include the significance of disinfection and sterilization work on the prevention and control of the nosocomial infection, the requirements of relevant laws and regulations, the basic principles and knowledge of disinfection and sterilization, and the occupational protection in disinfection and sterilization work.

4.3 The diagnosis and treatment instrument, appliances and items used by the medical institutions shall comply with the following requirements:

a) The diagnosis and treatment instrument, appliances and items entering into human body's aseptic tissue, organs, lacunae, OR contacting with the damaged skin, damaged mucosa, and tissue shall be sterilized;

b) The diagnosis and treatment instrument, appliances and items contacting with complete skin and intact mucosa shall be disinfected.

4.4 The disinfected products used by the medical institutions shall comply with the relevant national provisions, AND the relevant certificates of the disinfected products shall be reviewed and archived for reference.

4.5 The medical institutions shall maintain the clean and dry surface of the diagnosis and treatment environment, conduct timely and effective disinfection in the case of pollution; AND conduct regular disinfection against the departments of high infection risk.

4.6 The medical institutions shall, combining with the actual disinfection and sterilization work of the unit, provide the corresponding protective equipment for the workers engaging in the cleaning, disinfection and sterilization of the treatment instrument, appliance, and item, in order to protect the occupational safety of medical staff.

a) Critical items shall be subjected to the sterilization method;

b) Semi-critical items shall be subjected to the sterilization method which can reach the middle level above disinfection effects;

c) As for the non-critical items, it is preferable to use low level disinfection method or cleaning treatment; in case of pathogenic microbial contamination, effective disinfection method is selected based on the types of the contaminative pathogenic microorganisms.

5.2.2 The corresponding disinfection and sterilization method is selected based on the type and number of the contaminative microorganisms on the items:

a) As for the items which are contaminated by pathogenic bacteria spores, fungal spores, mycobacteria and transfusion transmitted pathogens (hepatitis B virus, hepatitis C virus, HIV, etc.), it shall use high level disinfection or sterilization;

b) As for the items which are contaminated by fungi, hydrophilic viruses, spirochetes, mycoplasma, chlamydia and other pathogenic microorganisms, it shall use the middle level above disinfection method;

c) As for the items which are contaminated by general bacteria and lipophilic virus and so on, it shall use the disinfection method which can reach to middle or low level;

d) In case of killing the microorganism which is protected by organic matters, it shall increase the use of disinfectant dosage and/or extend the disinfection time;

e) When the microorganism contamination of the disinfected item is particularly severe, it shall increase the use of disinfectant dosage and/or extend the disinfection time.

5.2.3 The corresponding disinfection and sterilization method is selected based on the nature of the disinfection items:

a) As for the heat-resistant and moisture-resistant medical instruments, appliances and items, it is preferable to select the pressure steam sterilization; the heat-resistant oil and dry powder be subjected to dry heat sterilization;

b) As for the items without heat and moisture resistant nature, it is preferable to use the low temperature sterilization methods such as ethylene oxide

6 Washing and cleaning

6.1 Scope of application

Washing is applicable to all the moisture-resistant treatment instruments, appliances and items; AND cleaning is applicable to all kinds of item surfaces.

6.2 Washing and cleaning methods

6.2.1 Washing: The reusable treatment instruments, appliances and items shall be timely recovered by the central sterile supply department (CSSD), AND sorted, washed, dried, checked, and serviced. Manual washing is applicable for the complex instruments, the treatment instruments with special requirements, the initial treatment of the instruments heavily contaminated by organic matters, AND in the absence of mechanical washing equipment, etc.; mechanical washing is applicable to the washing of most of the conventional equipment. The specific washing methods and precautions shall follow the requirements of WS 310.2.

6.2.2 Cleaning: The surfaces of the treatment wheels, diagnosis and treatment workbench, instrument & equipment deck, bedside cabinets, newborns warm case, and other items shall be wiped with cleaning towel or disinfection cloth towel. When wiping the items of different patient units, it shall replace the towels. A variety of wiping cloth towels and cleaning gloves shall be used in different areas, with a unified cleaning disinfection and dried to prepare for use.

6.3 Precautions

6.3.1 The items with chamber or with uneven surface shall, after being soaked in detergent, be carefully brushed manually or cleaned ultrasonically. The complex items which can be disassembled shall be cleaned after disassembly.

6.3.2 Cleaning water and detergent shall comply with the provisions of WS 310.1.

6.3.3 The manual cleaning tools such as brushes shall, after daily use, be cleaned and disinfected.

6.3.4 The cleaning of endoscopic and oral equipment shall follow the relevant national provisions.

6.3.5 As for the splash containing a small amount of blood or body fluids and other substances, it may be firstly cleaned and then disinfected; as for the splash of a large amount, it shall firstly use the moisture-absorbing material to remove visible contaminants AND then clean and disinfect it.

8.1.2.7 Power tools: They are divided in pneumatic tools and electric tools, which are generally composed of drill, saw blade, host machine, gas connection line, battery and other components. AND it shall follow the requirements of the user instructions to clean, pack and sterilize each part.

8.2 Sterilization of surgical dressings

8.2.1 Preparation before sterilization

8.2.1.1 The surgical dressings shall be stored in an environment of the temperature of 18 °C ~ 22 °C AND relative humidity of 35% ~ 70% before sterilization.

8.2.1.2 The cotton dressings can be packed in accordance with the requirements of YY/T 0698.2; the cotton yarn dressings can be packed by the medical paper bag, nonwoven cloth, wrinkled paper, or composite bags complying with YY/T 0698.2, YY/T 0698.4, and YY/T 0698.5, in the form of small package or single package.

8.2.2 Sterilization method

8.2.2.1 As for the cotton cloth dressings and cotton yarn dressings, it is preferable to select the pressure steam sterilization.

8.2.2.2 The surgical dressings complying with the requirements of YY/T 0506.1 shall be subjected to corresponding sterilization methods based on different materials.

8.3 Sterilization of surgical sutures

8.3.1 Surgical suture classification: It is divided into absorbable suture and non-absorbable suture. Absorbable sutures include ordinary gut, chrome gut, and synthetic absorbable suture and so on. Non-absorbable sutures include medical thread, polypropylene suture, polyester suture, nylon thread, metal wire and so on.

8.3.2 Sterilization method: Corresponding sterilization method is selected based on different materials.

8.3.3 Precautions: All sutures shall not be sterilized and used repeatedly.

8.4 Sterilization of other critical items

It shall use appropriate sterilization methods based on the materials of the items to be sterilized.

11.2.1.5 Terminal disinfection: It shall conduct terminal disinfection at the end of operation or when the patient is discharged, transferred to other hospital, or dead, by fumigation with 3% hydrogen peroxide or peracetic acid; the 3% hydrogen peroxide is in aerosol spray at 20 mL/m^3 AND the peracetic acid is for heating fumigation at 1 g/m^3 at the humidity of 70% ~ 90% in a sealed environment for 24 h; AND the 5% peracetic acid solution is in aerosol spray at 2.5 mL/m^3 at the humidity of 20% ~ 40%.

11.2.1.6 Fabrics: the bed sheets, quilt cover, and clothing, etc., used by the patients shall, if needing reuse, be specifically packed and sealed, with clear identification, and washed after pressure steam sterilization.

11.2.2 Precautions

11.2.2.1 It is preferable for the patients to use the disposable treatment instruments, appliances and items.

11.2.2.2 Medical personnel shall do well in occupational protection AND protection and isolation in accordance with the requirements of WS/T 311; they shall wear disposal gloves when contacting with patients, AND the hand hygiene shall comply with the requirements of WS/T 313.

11.2.2.3 Gauze, yarn pad and other dressings which are exposed to the wound of the patient, disposable medical supplies, and the cut tissues such as necrotic limbs, etc., shall be double sealed and packed and disposed as medical waste. The medical waste shall be disposed in accordance with the requirements of the Medical Waste Management Regulations.

11.3 Pathogens of sudden unexplained infectious diseases

The treatment instruments, equipment and items which are contaminated by the sudden unexplained infectious disease pathogens shall be disposed in accordance with the requirements of the current national regulations. In the absence of such requirements, the principle of disinfection is: if the transmission course is unknown, it shall determine the disinfection range and items based on multiple transmission courses; the disinfection dosage (it may be determined based on the dosage of killing spores) shall be determined based on the microorganism of strongest resistance of the microbial category to which the pathogens belongs; AND the medical staff shall do well in occupational protection.

12 Disinfection of skin and mucosa

12.1 Skin disinfection

12.2.2.2 USE the 3% (30 g/L) hydrogen peroxide to rinse the wound or wash the mouth, with the action reaching to the specified time.

12.2.2.3 USE the disinfectant containing 500 mg/L of available iodine to conduct rinsing, with the action reaching to the specified time.

12.2.3 Precautions

12.2.3.1 Other legal and effective mucosal and wound surface disinfection products shall be in accordance with the user instruction of product.

12.2.3.2 If it is indicated that the disinfectant is not applicable to pregnant women, it shall not be used for the disinfection of perineal and vaginal parts of pregnant women.

13 Cleaning and disinfection of ground and item surface

13.1 Cleaning and disinfection methods

13.1.1 Ground cleaning and disinfection: When the ground has no obvious contamination, it shall adopt wet cleaning. When the ground has been obviously contaminated by the patient's blood or body fluid, it shall firstly use the moisture-absorbing material to remove the visible contaminants AND then conduct cleaning and disinfection.

13.1.2 Cleaning and disinfection of item surface: If the indoor items such as table, chair, stool, bedside cabinet and other surfaces are not obviously contaminated, it shall adopt wet cleaning. If it is obviously contaminated, it shall firstly use the moisture-absorbing material to remove the visible contaminants AND then conduct cleaning and disinfection.

13.1.3 Cleaning and disinfection of the ground and item surface of the infectious high-risk department: As for the infectious high-risk departments such as surgery department (room), delivery room, catheter room, clean wards, bone marrow transplant wards, organ transplant wards, intensive care unit, newborn room, hemodialysis ward, burn ward, infectious disease, dentistry, laboratory, emergency and other wards and departments, the ground and item surfaces shall be kept clean and dry, disinfected every day, AND in the presence of obvious contamination, CONDUCT decontamination, cleaning and disinfection at any time. As for the ground disinfection, it shall use the chlorine disinfectant containing available chlorine of 400 mg/L ~ 700 mg/L to wipe it, with the action time reaching to 30 min. The item surface disinfection method is

Appendix A

(Normative)

Cleaning, disinfection and sterilization effects monitoring

A.1 Washing and cleaning effect monitoring

A.1.1 Washing effect monitoring of treatment instruments, appliances and items

A.1.1.1 Daily monitoring: It shall be conducted during inspection of the package through visual inspection and/or with the magnifying glass with light source. After cleaning, the instrument surface and its joints and teeth shall be clean AND free from blood stains, stains, water scale and other residual substances and rust.

A.1.1.2 Periodic random inspection: It shall randomly inspect the washing effects of all the items within at least 3 sterile package, with the inspection methods and contents same as that of daily monitoring, AND record the monitoring results.

A.1.1.3 As for the methods and sensitivity requirements for the washing and cleaning effect monitoring by protein residue measurement, ATP bioluminescence measurement and other methods, it shall regularly determine the protein residues on the treatment instruments, appliances and items OR the washing and cleaning effects.

A.1.2 Monitoring of washing disinfector and its effects

A.1.2.1 Daily monitoring

As for each batch, it shall monitor the physical parameters and operation of the cleaning disinfector, AND make records.

A.1.2.2 Regular monitoring

A.1.2.2.1 Cleaning effect of the washing disinfector can be monitored by the washing effect test indicators every year. When the washing items or procedures change, it may also use the washing effect test indicator to monitor the washing effects.

indicator bacterial tablet inoculated broth tube is in turbidity, the sterilization is disqualified; as for the broth tube hard to be judged, TAKE 0.1 mL make it inoculated in a nutrient agar plate; USE the sterilized L rod or inoculation ring to make it uniformly coated; PLACE it at 36 °C ± 1 °C to culture it for 48 h; OBSERVE the colony morphology, and CONDUCT smear microscopic examination to determine whether there is indicator bacteria growth. If there is indicator bacteria growth, the sterilization is disqualified; if there is no indicator bacteria growth, the sterilization is qualified;

f) Note: The bacteria tablet under monitoring shall obtain the disinfection product permit from the Ministry of Health, AND be used within the validity period.

A.2.3 Monitoring of hydrogen peroxide low temperature plasma sterilization and low temperature formaldehyde steam sterilization effect

Hydrogen peroxide low temperature plasma sterilization and low temperature formaldehyde steam sterilization effect monitoring shall follow the requirements of WS 310.3.

A.2.4 Monitoring of ethylene oxide gas sterilization effect

A.2.4.1 The physical monitoring method, chemical monitoring method and biological monitoring method for ethylene oxide gas sterilization shall follow the requirements of WS 310.3.

A.2.4.2 The production of conventional biological test packages is as follows:

a) Standard indicator strains: Bacillus subtilis black variant spores, with the bacteria tablet composition and resistance complying with the relevant national standards;

b) Production method of conventional biological test package: TAKE a 20 mL sterile syringe; REMOVE the needle; PULL out the pintle; PLACE the standard biological indicator bacteria into the cylinder, with the perforated plastic cap toward the needle; INSERT the pintle of the syringe back into the cylinder (be careful not to touch the biological indicator); then USE a cotton towel to wrap it in two layers; PLACE it in the paper-plastic packaging bag; SEAL it;

c) Monitoring method: PLACE the conventional biological test package on the most difficult sterilized part of the sterilizer (the center of the entire loaded sterilization package). After the completion of the sterilization cycle, immediately TAKE the indicator bacteria tablet out and MAKE it inoculated in the 0.5% 0.5% glucose broth culture medium tube

PLACE the sample tube on the mixer for oscillation for 20 s OR vigorously SHAKE it for 80 times; USE the sterile pipette to absorb 1.0 mL of sample under detection and INOCULATE it in the sterilization plate, with each plate inoculated into two plates; ADD 15 mL ~ 18 mL of the melted 45 °C ~ 48 °C nutrient agar into the plates; SHAKE it uniformly while adding it; when the agar is solidified, PLACE it in a 36 °C ± 1 °C incubator for culture for 48 h; COUNT the number of colonies.

The total number of bacterial colonies is calculated in accordance with the equation (A.1):

$$\text{Total number of bacterial colonies (CFU/cm}^2\text{)} = \frac{\text{Number of colonies on plate x dilution factor}}{\text{Sampling area}} \quad \cdots\cdots\cdots\cdots (A.1)$$

A.4.2.4 Result judgment

The judgment criteria for skin disinfection effects shall follow the surgical hand disinfection requirements of WS/T 313.

A.4.2.5 Precautions

If the sampling skin surface is less than 5 cm × 5 cm, it may use the specification plate of corresponding area to take sample.

A.5 Monitoring of item surface disinfection effect

A.5.1 Sampling time

CONDUCT sampling after disinfection or suspected to be associated with a hospital infection outbreak.

A.5.2 Sampling method

USE the 5 cm × 5 cm sterilization specifications plate; PLACE it on the item under detection; USE one cotton swab soaked with sterile 0.03 mol/L phosphate buffer (PBS) or saline solution to rub uniformly along the specification plate transversely and longitudinally for 5 times respectively; ROTATE the cotton swab; continuously SAMPLE 4 specification plate areas; if the area under sampling is < 100 cm^2, TAKE all the surface; if the area under sampling is ≥ 100 cm^2, TAKE 100 cm^2. CUT the hand touched parts; PLACE the cotton swab into a 10 mL sterile elution test tube containing corresponding neutralizer; SEND for inspection. As for the small items such as door handle, USE cotton swab to directly smear the item surface to take sample; AND if the sampled item surface has disinfectant residue, the sampling solution shall contain corresponding neutralizer.

medical treatment activities; OR it shall be sampled once suspected to be associated with hospital infection breakout.

A.6.2 Monitoring method

A.6.2.1 Clean operation department (room) and other clean room may choose sedimentation method or floating bacteria method, with reference to the requirements of GB 50333 for monitoring. The floating bacteria method may select six-stage impact air sampler or other certified air sampler. During monitoring, PLACE the sampler in the center part indoor at the height of 0.8 m ~ 1.5 m, or otherwise FOLLOW the sampler instructions, with each sampling time not more than 30 min. As for the room with area > 10 m^2, ADD one additional sampling point for each area increase of 10 m^2.

A.6.2.2 The room where the air is not cleaned by the clean technology adopts the settlement method: if the indoor area is less than or equal to 30 m^2, SET three points on the internal, middle and external diagonal lines, with the distance from the internal and external points to the wall of 1 m; if the indoor area > 30 m^2, SET five points (four corners and the center), with the points at four corners 1 m away from the wall. PLACE the ordinary nutrient agar plate (Φ90 mm) at each sampling point, with the sampling height 0.8 m ~ 1.5 m from the ground. During sampling, OPEN the plate cover and PLACE it aside the plate; after exposure for the specified time, COVER the plate and SEND it for test in time.

A.6.2.3 PLACE the tested plate in the 36 °C ± 1 °C incubator for culture for 48 h; COUNT the number of colonies. If suspected to be associated with a hospital infection breakout, CONDUCT the target microbiological detection.

A.6.3 Result calculation

A.6.3.1 Settlement method is reported based on the average number of colonies per plate: CFU/(plate • exposure time).

A.6.3.2 Calculation equation of floating bacteria method is as shown in equation (A.3):

$$\text{Total number of bacterial colonies in the air (CFU/cm}^3\text{)} = \frac{\text{Sum of the number of colonies on each plate of the sampler (CFU)}}{\text{Sampling rate (L/min) x sampling time (min)}} \times 1\,000 \quad \cdots\cdots(A.3)$$

A.6.4 Result judgment

A.6.4.1 As for the clean operation department (room) and other clean places, the total number of bacterial colonies in the air shall comply with GB 50333.

Appendix B

(Informative)

Disinfection test reagents and medium formulations

B.1 Phosphate buffer (PBS, 0.03 mol/L, pH 7.2)

Anhydrous disodium hydrogen phosphate: 2.83 g

Potassium dihydrogen phosphate: 1.36 g

Distilled water was added to: 1000 mL

ADD each ingredient into 1000 mL of distilled water; after it is completely dissolved, ADJUST the pH to 7.2 ~ 7.4; MAKE it subjected to 121 °C pressure steam sterilization for 20 min; PREPARE for use.

B.2 Sterile test eluent

Tween-80: 1 g

Peptone: 10 g

Sodium chloride: 8.5 g

Distilled water: 1000 mL

ADD each ingredient into 1000 mL of 0.03 mol/L PBS solution; after heating for dissolution, ADJUST the pH to 7.2 ~ 7.4; MAKE it subjected to 121 °C pressure steam sterilization for 20 min; PREPARE for use.

B.3 Nutrient agar medium

Peptone: 10 g

Beef: 5 g

Sodium chloride: 5 g

Agar: 15 g

Distilled water: 1000 mL

Appendix C

(Normative)

Commonly used disinfection and sterilization methods

C.1 Pressure steam sterilization

C.1.1 Scope of application

It is applicable to the sterilization for heat-resistant and moisture-resistant treatment instruments, appliances and items sterilization. The bottom exhaust pressure steam sterilization is also suitable for liquid sterilization; AND the rapid pressure steam sterilization is suitable for the sterilization for heat-resistant and moisture-resistant treatment instruments, appliances and items. Pressure steam sterilization is not suitable for sterilization of oils and powders.

C.1.2 Classification

Based on the differences of cold air exhaust method and degree, it is divided into the bottom exhaust pressure steam sterilizer AND the pre-exhaust pressure steam sterilizer. Depending on the length of the sterilization time, the pressure steam sterilization procedure includes conventional pressure steam sterilization procedures and rapid pressure steam sterilization procedures.

C.1.3 Sterilization method

C.1.3.1 Bottom exhaust pressure steam sterilization

The bottom exhaust pressure steam sterilizer includes portable pressure steam sterilizer and horizontal pressure steam sterilizer. The sterilization procedure generally includes front exhaust, sterilization, rear exhaust and drying, etc. The actual operation method shall follow the manufacturer's instructions or instruction manual. The sterilization parameters of sterilizer are generally temperature 121 °C, pressure 102.9 kPa, instrument sterilization time 20 min, AND dressing sterilization time 30 min.

C.1.3.2 Pre-exhaust pressure steam sterilization

The sterilization procedures of sterilizer generally include more than 3 times of the pre-vacuum and pulsating exhaust (such as inflation), sterilization, rear exhaust and drying, etc. the specific method of operation to follow the

items, and the monitoring of sterilization effects. Specific procedures shall follow the requirements of WS 310.2.

C.2 Dry heat sterilization

C.2.1 Scope of application

It is applicable to the sterilization of the heat and moisture resistant items through which steam or gas cannot penetrate, such as the sterilization of glass, metal and other medical supplies and oil, powder and other products.

C.2.2 Sterilization method

USE the dry heat sterilizer to conduct sterilization, with the sterilization parameters generally: 150 °C, 150 min; 160 °C, 120 min; 170 °C, 60 min; and 180 °C, 30 min.

C.2.3 Precautions

C.2.3.1 During sterilization, the item under sterilization shall not contact with the internal bottom and wall of the sterilizer; after sterilization and when the temperature is reduced to 40 °C, OPEN the sterilizer cabinet door.

C.2.3.2 The sterilization package volume shall not exceed 10 cm × 10 cm × 20 cm; the oil and powder thickness shall not exceed 0.6 cm; the vaseline gauze strip thickness shall not exceed 1.3 cm; the loading height shall not exceed 2/3 of the inner cavity of the sterilizer; AND clearance shall be reserved between items.

C.2.3.3 When setting the sterilization temperature, it shall fully consider the resistance of the item under sterilization to the temperature; AND when the organic items or items with paper packages, the temperature shall be ≤ 170 °C.

C.2.3.4 When the sterilization temperature reaches to the requirements, it shall turn on the ventilator device of the cabinet.

C.2.3.5 Sterilization operation shall follow the manufacturer's instructions or instruction manual.

C.3 Ethylene oxide gas sterilization

C.3.1 Scope of application

It is suitable for the sterilization of the non-heat resistant and non-moisture resistant treatment instruments, appliances and items such as electronic instruments, optical instruments, paper products, chemical fiber products,

basket or metal mesh frame; AND the paper-plastic package shall be placed sidewise.

C.3.4.2 The loading of items shall not exceed 80% of the total volume of the cabinet.

C.3.5 Precautions

C.3.5.1 Sterilizer installation shall comply with the requirements, including well ventilation, away from fire source, and reservation of 51 cm at any sides of the sterilizer (including above). It shall install dedicated exhaust pipe, AND be completely isolated from the other exhaust pipes of the building.

C.3.5.2 It shall have dedicated exhaust pipe system which is made of non-permeable ethylene oxide material such as brass or the like, AND sump shall be fitted when the perpendicular portion length exceeds 3 m. Exhaust pipe shall be led to the outside, AND reverse downwards at the outlet; there shall be no inflammable or explosive matters OR building air inlets such as door or window within the range 7.6 m away from the exhaust port; AND the exhaust pipe shall have no depression or loop.

C.3.5.3 The ethylene oxide sterilization cylinders or gas cylinders shall be kept away from fire and static electricity, well ventilated, free from sun exposure, and at the preservation temperature less than 40 °C; AND they shall not be placed in refrigerator. They shall be disposed strictly in accordance with the national storage requirements for inflammable and explosive items.

C.3.5.4 It shall conduct annual monitoring and recording of ethylene oxide concentrations in the working environment. In the daily 8 h work, the ethylene oxide concentration TWA (time weighted average concentration) shall not exceed 1.82 mg/m^3 (1 ppm).

C.3.5.5 Sterilization workers shall be trained of professional knowledge and emergency treatment. After excessive exposure to ethylene oxide, they shall be immediately moved away from poisoning scene AND make them immediately inhale fresh air; after skin contact, USE water to rinse the skin contact portion for at least 15 min, and meanwhile TAKE off dirty clothes; in case of eye contact with liquid ethylene oxide or high concentration epoxy ethane gas, RINSE eyes for at least 10 min, and SEEK doctors as soon as possible.

C.3.5.6 It shall be carried out in the ethylene oxide sterilizer, AND the sterilizer shall obtain the disinfection product permit from the Ministry of Health.

C.4 Hydrogen peroxide low temperature plasma sterilization

penetrate such as cloth, ordinary paper, polyethylene film, cellophane and so on.

C.5.3.6 When loading, the sterilization items shall be spread out, leaving a certain gap in the middle, AND the surface of the item shall be exposed as much as possible. When using paper-plastic packaging materials, the packaging shall be erected AND the paper shall be arranged facing the plastic in order.

C.5.3.7 After disinfection, it shall eliminate the residual formaldehyde gas through ventilation or ammonia neutralization.

C.6 UV disinfection

C.6.1 Scope of application

It is suitable for indoor air and item surface disinfection.

C.6.2 UV disinfection lamp requirements

C.6.2.1 At the voltage of 220 V, the relative humidity of 60%, the temperature of 20 °C, AND the radiation of 253.7 nm, the UV intensity (the intensity in use) of the UV disinfection lamp shall not be less than 70 $\mu W/cm^2$.

C.6.2.2 It shall regularly monitor the irradiation intensity of the disinfection ultraviolet radiation. When the irradiation intensity is reduced below the required value, it shall be replaced in time.

C.6.2.3 The life of the UV disinfection lamp, that is, the time when the intensity of the new lamp is reduced to 70 $\mu W/cm^2$ (power ≥ 30 W) OR reduced to 70% of the original lamp intensity (power < 30 W) shall be not less than 1000 h. The UV lamp manufacturer shall provide the actual service life.

C.6.3 Use methods

C.6.3.1 In the indoor unmanned state, USE the hanging or mobile type ultraviolet light to conduct direct disinfection; the lamp tube is 1.8 m ~ 2.2 m above ground; AND the average number of the installed UV lamps is ≥ 1.5 W/m^3, with the irradiation time ≥ 30 min.

C.6.3.2 USE the ultraviolet disinfector to disinfect the air and item surface; AND the disinfection methods and precautions shall follow the manufacturer's instructions.

C.6.3.3 Requirements for environment during disinfection: When the UV light directly irradiates the disinfection air, CLOSE door and window and KEEP the

protective film, and then removed of grease through the detergent, dried, AND disinfected and sterilized in time.

C.8.1.3.2 Glutaraldehyde is toxic to humans AND it shall be used in a well-ventilated environment. It is irritating to the skin and mucous membranes, so it shall pay attention to personal protection when using it. In case of accident contact, it shall immediately use clean water to continue rinsing it AND seek doctor if necessary.

C.8.1.3.3 Glutaraldehyde shall not be used for item surface wiping or spray sterilization, indoor air disinfection, hand & skin OR mucous membrane disinfection.

C.8.1.3.4 Before using the enhanced acid glutaraldehyde, it shall firstly add the pH regulator (sodium bicarbonate); AND then add the anti-rust agent (sodium nitrite); Mix it thoroughly.

C.8.1.3.5 The vessel for soaking sterilization shall be clean, sealed, and subjected to sterilization treatment before use.

C.8.1.3.6 At the temperature of 20 °C ~ 25 °C, the continuous use time of glutaraldehyde solution added with pH regulator and sodium nitrite shall be ≤ 14 d.

C.8.1.3.7 It shall ensure that the concentration of glutaraldehyde in use complies with the requirements of the user instructions of product.

C.8.1.3.8 Glutaraldehyde shall be sealed, protected from light, AND placed in a cool, dry, and well-ventilated environment.

C.8.2 O-phthalaldehyde

C.8.2.1 Scope of application

It is suitable for the soaking disinfection of the non-heat resistant treatment instruments, appliances and items.

C.8.2.2 Use methods

C.8.2.2.1 Completely SOAK the treatment instruments, appliances and items to be disinfected into the 5.5 g/L o-phthalaldehyde solution of pH 7.0 ~ 8.0 and temperature 20 °C ~ 25 °C; COVER the disinfection vessel; MAKE it act for 5 min ~ 12 min.

C.8.2.2.2 Disinfection for endoscopy shall follow the relevant national requirements.

peracetic acid to the required concentration. The calculation method and preparation procedures are as follows:

a) CALCULATE the volume (V_1) of the required peracetic acid stock solution: $V_1 = (c_2 \times V_2) / c_1$;

b) CALCULATE the volume of the required distilled water (V_3): $V_3 = V_2 - V_1$;

c) TAKE peracetic acid stock solution V_1 (mL); ADD distilled water V_3 (mL); MIX it uniformly.

C.9.1.2.2 Disinfection methods

C.9.1.2.2.1 Soaking method：SOAK the items to be sterilized in a vessel containing peracetic acid; and CAP it. As for the general item surface, USE 0.1% ~ 0.2% (1000 mg/L ~ 2000 mg/L) peracetic acid solution to soak it for 30 min. As for the high level disinfection of corrosion-resistant treatment instruments, USE the 0.5% (5000 mg/L) peracetic acid to rinse it for 10 min; TAKE it out using the sterile method; USE sterile water to wash it clean; USE sterile towel to wipe it dry; PREPARE for use.

C.9.1.2.2.2 Wipe method: The large items or other items that cannot be sterilized by soaking method are sterilized by wiping. The concentration and action time used for the disinfection are same as those of the soaking method.

C.9.1.2.2.3 Sprinkling method: As for environmental disinfection, USE 0.2% ~ 0.4% (2000 mg/L ~ 4000 mg/L) peracetic acid solution to sprinkle and MAKE it action for 30min ~ 60min.

C.9.1.2.2.4 Spraying method: USE the electric ultra-low capacity sprayer and the 5000 mg/L peracetic acid solution to conduct spraying disinfection at the consumption of 20 mL/m^3 ~ 30 mL/m^3, with the action time for 60 min.

C.9.1.2.2.5 Fumigation method: USE the 15% peracetic acid (7 mL/m^3) to conduct heating and evaporation, at the relative humidity of 60% ~ 80%, for room temperature fumigation for 2 h.

C.9.1.2.2.6 When sterilizing endoscopy with special mechanical disinfection equipment with peracetic acid as sterilizing agent, it shall follow the application scope and operation method of the disinfection product permit from the Ministry of Health.

C.9.1.3 Precautions

C.9.1.3.1 Peracetic acid is unstable AND it shall be stored in a cool and well-ventilated place away from combustible materials. Before use, it shall

C.9.3.3.1 It shall be stored in a dry and well-ventilated place.

C.9.3.3.2 Diluent shall be prepared when using, with the validity period ≤ 24 h.

C.9.3.3.3 It has medium corrosion against carbon steel and aluminum, AND slight corrosion against copper and stainless steel. The metal products shall, after being subjected to chlorine dioxide disinfection, be promptly rinsed with qualified water and dried.

C.10 Chlorine disinfectant

C.10.1 Scope of application

It is applicable to the disinfection of items, item surfaces, secretions, excreta and so on.

C.10.2 Use methods

C.10.2.1 Disinfectant preparation

Based on the available chlorine content of the product AND in accordance with the dilution law, USE distilled water to dilute it to the required concentration. The specific calculation methods and preparation procedures are as shown in C.9.1.2.1.

C.10.2.2 Disinfection methods

C.10.2.2.1 Soaking method: SOAK the items to be sterilized in a vessel containing a chlorine disinfectant solution and CAP it. The items contaminated by the bacterial propagules shall be disinfected by soaking in the disinfectant containing available chlorine 500 mg/L for more than 10 min; AND the items contaminated by menstrual transmission pathogens, mycobacteria and bacterial spores be disinfected by soaking in the disinfectant containing available chlorine 2000 mg/L ~ 5000 mg/L for more than 30 min

C.10.2.2.2 Wipe method: The large items or other items that cannot be sterilized by soaking method are sterilized by wiping. The concentration and action time used for the disinfection are same as those of the soaking method.

C.10.2.2.3 Spraying method: The generally contaminated item surfaces shall be uniformly sprayed with the disinfectant containing available chlorine of 400 mg/L ~ 700 mg/L, with the action time of 10 min ~ 30 min; AND the item surfaces contaminated by meningeal pathogens, mycobacterium tuberculosis and so on shall be uniformly sprayed with the disinfectant containing available chlorine of 2000 mg/L, with the action time more than 60 min. After spraying, there will be a strong irritating smell, so personnel shall leave the site.

C.11.2.4 Disinfection of treatment instruments: PLACE the items to be disinfected into the 70% ~ 80% (volume ratio) ethanol solution for disinfection ≥ 30 min and CAP it; or otherwise CONDUCT surface wiping disinfection.

C.11.3 Precautions

C.11.3.1 Alcohol is flammable AND it shall not have open flames.

C.11.3.2 It shall not be used for the disinfection of surfaces seriously contaminated by organic matters such as blood, pus, feces and so on.

C.11.3.3 After use, it shall be caped closely, sealed, AND preserved in a cool place.

C.11.3.4 Those with alcohol allergy shall use it with caution.

C.12 Iodine-containing disinfectant

C.12.1 Iodophor

C.12.1.1 Scope of application

It is applicable to the disinfection of hand, skin, mucous membranes and wound.

C.12.1.2 Use methods

C.12.1.2.1 Disinfectant preparation

When rinsing mucosa, based on the available iodine content, USE the sterile distilled water or purified water to dilute the iodophor to the required concentration in accordance with the law of dilution. The specific calculation methods and preparation procedures are as shown in C.9.1.2.1.

C.12.1.2.2 Disinfection methods

C.12.1.2.2.1 Wipe method: As for the skin and mucosa wipe disinfection, USE the sterile cotton balls or other alternative items soaked with iodophor disinfectant liquid to wipe the disinfection areas. As for the surgical hand disinfection, USE the iodophor disinfectant stock solution to wipe and rub for at least 3 min. As for the skin disinfection at surgical part, USE the iodophor disinfectant stock solution to wipe locally for 2 ~ 3 times, with the action time at least for 2 min. As for the skin disinfection at injection part, USE the iodophor disinfectant stock solution to wipe locally for 2 ~ 3 times, AND the action time shall be in accordance with the user instruction of product. As for the oral mucosa and wound disinfection, USE the iodophor containing available iodine 1000 mg/L ~ 2000 mg/L to wipe it, with the action time of 3 min ~ 5 min.

application as specified by the disinfection product permit from the Ministry of Health.

C.12.3.2 Use methods

C.12.3.2.1 The compound iodine disinfectant containing ethanol or isopropyl alcohol can be used for hand and skin disinfection: using the stock solution to wipe it for 1 ~ 2 times with the action time 1 min ~ 2 min; BUT it shall not be used for mucosal disinfection.

C.12.3.2.2 The applications of the compound povidone-iodine disinfectant containing chlorhexidine are same as those of the common iodine disinfectant, it shall follow the instruction of this disinfectant permit approved by health administrations, AND it shall be used for abdominal rinse disinfection in caution.

C.12.3.3 Precautions

It is same as iodophor, And during use, it shall pay attention to the side effects of the compound substances.

C.13 Chlorhexidine

C.13.1 Scope of application

It is applicable to hand, skin, and mucosal disinfection.

C.13.2 Use methods

C.13.2.1 Disinfectant preparation

USE the sterile distilled water or purified water to dilute the disinfectant into the required concentration based on the available content. The specific calculation methods and preparation procedures are as shown in C.9.1.2.1. Generally the stock solution is directly used.

C.13.2.2 Disinfection methods

C.13.2.2.1 Wipe method: The skin and wound surface of the surgical parts and the injection parts shall be disinfected by the chlorhexidine-ethanol (70%, volume ratio) solution with the effective content of ≥ 2 g/L for local wiping for 2 ~ 3 times, AND the action time shall follow the user instruction of the product; AND the surgical hand shall be disinfected by the chlorhexidine-ethanol (70%, volume ratio) solution with the effective content of ≥ 2 g/L, AND the action time shall follow the user instruction of the product.

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