

**On approval of Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control”**

***Invalidated***
***Unofficial translation***

Order of the Minister of Health of the Republic of Kazakhstan dated August 28, 2018 No. Р DSM-8. Registered in the Ministry of Justice of the Republic of Kazakhstan on September 25, 2018 No. 17429.Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated July 29, 2022 No. KR DSM-68

      *Unofficial* *translation*

      Footnote. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated July 29, 2022 No. KR DSM-68 (effective sixty calendar days after the date of its first official publication).

      In accordance with paragraph 6 of Article 144 of the Code of the Republic of Kazakhstan “On Public Health and Healthcare System” as of September 18, 2009, **I hereby ORDER**:

      1. To approve the appended Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control” in accordance with Appendix 1 to this order.

      2. To invalidate some orders of the Minister of National Economy of the Republic of Kazakhstan in accordance with Appendix 2 to this order.

      3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Public Health Protection Committee of the Ministry of Healthcare of the Republic of Kazakhstan shall:

      1) ensure state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

      2) within ten calendar days of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, send its electronic copy in Kazakh and Russian to the Republican State Enterprise with the Right of Economic Management “Republican Center of Legal Information” for its official publication and inclusion into the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan;

      3) place this order on the official website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

      4) within ten working days of the state registration of this order, submit information on the implementation of measures, provided for in subparagraphs 1), 2) and 3) of this paragraph to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan.

      4. Control over execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

      5. This order shall take effect twenty-one calendar days after its first official publication.

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*Minister of Healthcare of*
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*the Republic of Kazakhstan*
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*Y.Birtanov*
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      "AGREED"

      Minister of Education and Science of

      the Republic of Kazakhstan

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Y.Sagadiyev

      " " 2018

      "AGREED"

      Minister of National Economy of

      the Republic of Kazakhstan

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ T.Suleimenov

      " " 2018

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|   | Appendix 1 toOrder № ҚР ДСМ-8 of theMinister of Healthcare of theRepublic of Kazakhstan as ofAugust 28, 2018 |

 **Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct**
**of disinfection, pest and rodent control”**
**Chapter 1. General provisions**

      1. These Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control” (hereinafter referred to as Sanitary Rules) establish sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control to entities of any type, public or private.

      2. The following basic concepts are used in these Sanitary Rules:

      1) current disinfection – disinfection on a regular basis for every nosological form, while a patient is in a focus of disease;

      2) gnat - common name of a group of bloodsucking flying insects (mosquitoes, gadflies, black flies, biting midges, sand flies) that cause harm to human health;

      3) field pest control - extermination of bloodsucking insects and ticks outside a populated locality to reduce their number in general or to create protective zones around public places;

      4) field rodent control - extermination of rodents to reduce their number and prevent the development of epizootics of diseases dangerous to humans;

      5) disinfection - a set of special measures aiming to exterminate agents of infectious and parasitic diseases in the external environment;

      6) disinfection equipment - devices and installations intended for disinfection, pre-sterilization cleaning, sterilization, pest and rodent control;

      7) disinfectants - chemical and biological agents intended for disinfection (disinfecting agents), pre-sterilization cleaning, sterilization (sterilizing agents), pest control (insecticides), rodent control (rodenticides), and also repellents and pediculicides;

      8) pest control - a set of preventive and exterminatory measures for the eradication of insects and arthropods in order to protect people, animals, premises and territory from them;

      9) rodent control - a set of preventive and exterminatory measures aimed at eradicating rodents or reducing their number;

      10) high-level disinfection – disinfection completely exterminating all pathogenic and opportunistic microorganisms and reducing the number of spores;

      11) imago - adult (mature) stage of development of arthropods;

      12) insecticides (acaricides, insectoacaricides) - chemical agents (preparations) used to kill insects and ticks;

      13) chamber disinfection - disinfection and pest control in disinfection chambers;

      14) barrier rodent control - creation of a buffer zone at least 200 meters wide around permanent or temporary populated localities, as well as in recreation areas, health facilities for the extermination of rodents using any current method (physical, chemical, biological) to prevent migrations of rodents, infection carriers;

      15) village pest control - eradication of harmful insects, ticks and other arthropods within a populated locality;

      16) village rodent control - eradication of rodents in residential premises (buildings), outbuildings, livestock, industrial, warehouse and other premises, and also outdoors within a populated locality;

      17) mode of application - a set of norms characterizing the use of a disinfectant, including the concentration of active substance in the used preparative form, the consumption of the preparation, the treatment time, frequency and area of treatments, the use of auxiliary substances and methods;

      18) final disinfection – disinfection conducted in a focus after hospitalization, isolation, recovery or death of a patient;

      19) intermediate-level disinfection – disinfection eradicating bacteria (including mycobacterium tuberculosis), viruses (including polioviruses), fungi, but not spores;

      20) focus - a place of stay of a patient having an infectious or parasitic disease together with the surrounding area within the limits of possible transmission of an infectious agent from the patient to susceptible people;

      21) focal disinfection - disinfection conducted in foci to prevent and (or) eradicate infectious and parasitic diseases;

      22) preparative form - the form of disinfectants’ release and (or) use;

      23) repellents - chemical agents that repel arthropods or rodents;

      24) rodenticides (raticides) - preparations (agents) for rodent control;

      25) sterilization - complete eradication of all types of pathogens, including spores, using physical, chemical, thermal or mixed methods;

      26) low-level disinfection - disinfection, which eradicates bacteria, some fungi, viruses, but useless against such resistant bacteria as mycobacterium tuberculosis.

      3. Disinfection, pest and rodent control measures are carried out in accordance with Article 152 of the Code of the Republic of Kazakhstan “On Public Health and Healthcare System” as of September 18, 2009 (hereinafter referred to as the Code).

      4. Adults without contraindications for health reasons are allowed to work with disinfectants. Once every five years, specialists employed to work with disinfectants (disinfection instructor, disinfector, rodent exterminator) shall take professional training in disinfection, pest and rodent control and shall be annually briefed on safe performance of works, first aid in case of poisoning with disinfectants.

      5. Disinfectants shall be stored and transported in accordance with paragraph 3 of Article 156 of the Code.

      6. Disinfectants shall be stored in the supplier’s tare (packing materials) with the indication of the agent’s name, its purpose, and expiration date on the label. The tare label shall be in place for the entire period of the disinfectant’s storage (use).

      7. For disinfection, pest and rodent control, it is allowed to apply agents permitted for use in the Republic of Kazakhstan and the Eurasian Economic Union. The danger of disinfectants is established according to the hazard classification of disinfectants, insecticides, rodenticides specified in Appendix 1 to these Sanitary Rules. Conditions under which disinfectants shall be used depend on the degree of their danger:

      1) extremely hazardous agents may not be used in enclosed areas (class 1);

      2) highly hazardous agents (class 2) may not be used in educational institutions, educational institutions for orphaned children, children without parental care, health facilities, public catering facilities and residential premises. In other places, they may only be used by trained personnel while other people are absent, and it is mandatory to do airing and cleaning after their use (class 2);

      3) moderately hazardous agents (class 3) may be used by trained personnel in premises of any type and by people in everyday life, but with mandatory rules for the observance of conditions of their use (consumption of the preparation, ventilation mode, cleaning);

      4) low hazardous agents (class 4) may be used without limiting the scope of application.

      8. In case of expiration of disinfectants’ shelf life, signs of their uselessness (discoloration, presence of alien elements), they shall be written off and destroyed.

      Chapter 2. Sanitary and epidemiological requirements for the organization and conduct of disinfection

      9. Disinfection in enclosed areas using the methods of irrigation, dusting, wiping with preparations having an irritant effect and causing allergic reactions is only allowed while other people are absent.

      10. The consumption of disinfectants for disinfecting individual items shall be calculated on the basis of the rates for planning disinfectants for disinfecting individual items specified in Appendix 2 to these Sanitary Rules.

      11. Current disinfection in the focus of an infectious disease is carried out from the moment of the patient’s detection until his/her hospitalization, in case of home treatment - until his/her recovery, in case of convalescents and bacteria carriers - until their full recovery.

      12. Current disinfection shall be organized by a health worker of a health facility and carried out by a person caring for a sick person, a convalescent or bacterial carrier.

      13. Final disinfection shall be carried out by disinfection stations or disinfection departments (units), state-run organizations operating in the field of sanitary and epidemiological welfare of the population.

      14. Final disinfection in the foci of infectious and parasitic diseases shall be carried out within one day of the patient’s hospitalization, isolation, recovery or death.

      15. An application for final disinfection in the foci of infectious diseases shall be submitted over the phone by a specialist of the state body of the sanitary and epidemiological service in the field of sanitary and epidemiological welfare of the population to the departments (units) of state-run organizations operating in the field of sanitary and epidemiological welfare of the population, disinfection stations, antiplague facilities after the patient’s isolation, hospitalization, changes in his/her diagnosis, his/her death.

      16. The health facility’s need for disinfectants shall be calculated in accordance with Appendix 3 to these Sanitary Rules.

      17. The observance of the modes of disinfection and sterilization is assessed as satisfactory by such indicators as:

      1) the seeding of non-pathogenic microflora from monitored items in not more than 5 percent (hereinafter referred to as %) of selected bacteriological washings made within 50 minutes of current disinfection;

      2) observance of the concentration of disinfectant solutions recommended by instructions for use;

      3) identification of unsatisfactory rapid tests for residual disinfectants in not more than 5% of samples of each type;

      4) compliance of the bacteriological test control with the chamber disinfection mode;

      5) no positive tests for residual blood;

      6) no positive tests for residual alkaline components of synthetic detergents and residues of oily medicines;

      7) appropriate sterilization mode, absence of non-sterile materials (complete eradication of vegetative and spore forms of microorganisms).

      18. The quality of current disinfection in foci is assessed by specialists of territorial divisions of the department of the state body in the field of sanitary and epidemiological welfare of the population using laboratory methods in at least 5% of foci, taking at least 10 bacteriological washings in one focus, 1 sample (dry substance), 1 sample of the working solution of disinfectants.

      19. The quality of disinfection is considered satisfactory, if the number of positive washings for the presence of non-pathogenic microflora doesn’t exceed 3% of selected washings, the number of negative rapid tests for the presence of a residual disinfectant is not more than 5%, the number of unsatisfactory analyses of disinfectant solutions is lower than 5% of selected samples.

      20. When seeding pathogenic microflora after final disinfection, the latter is considered unsatisfactory and shall be repeated again, followed by disinfection quality control.

      21. The quality of the organization of final disinfection is assessed by such indicators as:

      1) the treatment of at least 95% of infectious foci subject to final disinfection;

      2) timeliness of final disinfection - at least 95% (final disinfection in infectious foci was carried out within one day of hospitalization or isolation of a patient from an organized team);

      3) the treatment of at least 95% of foci subject to chamber disinfection;

      4) quality control of final disinfection of foci:

      in case of visual inspection – of at least 10% of all disinfections performed. Using laboratory methods – in at least 10% of all foci within the period of 1 to 3 hours after the disinfection is over.

      22. To assess the quality of disinfection at health facilities, it is necessary:

      1) to determine the quality of disinfection by selecting washings from items and equipment in hospitals - 0.3% of a washing per bed, but not less than 30 washings, in outpatient facilities – 0.2% of a washing per visit;

      2) to examine samples of disinfectants, working solutions of disinfectants - at least 2 samples of different types. When sampling, it is necessary to mark the date of sampling, the date of preparation of a disinfecting solution, its concentration, purpose of use;

      3) to determine the operating efficiency of disinfection chambers by laying 5-10 bacterial (chemical) tests in the chamber’s three planes, depending on its type and volume. The assessment of the quality of sterilization requires the observance of conditions of sterilization, sterility of medical devices and air.

      23. The air inside surgical hospitals (departments) is disinfected as follows:

      1) with ultraviolet radiation using open and combined bactericidal irradiators, used in the absence of people, and closed irradiators, including recirculators, allowing to disinfect air in the presence of people;

      2) with disinfecting sprays in the absence of people using special spraying equipment (aerosol generators) during final disinfection;

      3) with ozone using installations-ozone generators in the absence of people during final disinfection and overall cleaning;

      4) using antimicrobial filters.

      24. After a patient is discharged from a hospital, his/her bedding is subject to chamber disinfection. Mattresses and pillows in hermetically sewn hygienic covers are disinfected by wiping and irrigating covers with disinfectants.

      25. The quality of disinfection, sterilization, and the preparation of biological tests shall be assessed by state-run organizations operating in the field of sanitary and epidemiological welfare of the population.

      Chapter 3. Sanitary and epidemiological requirements for the organization and conduct of disinfection, pre-sterilization cleaning, sterilization and storage of medical devices

      26. Medical equipment and medical devices (hereinafter referred to as MDs) are divided into three groups according to the degree of their contact with human body and the risk of infecting a patient:

      1) critical MDs - tools and equipment in direct contact with human tissues, cavities or bloodstream;

      2) semi-critical MDs - tools and equipment in contact with intact mucous membranes;

      3) non-critical MDs - tools, equipment and items of care in contact with intact skin.

      Critical MDs shall be sterilized, semi-critical ones shall be disinfected at high and intermediate levels, non-critical ones shall be disinfected at intermediate and low levels.

      27. Disinfection and pre-sterilization of MDs are carried out in accordance with Appendices 4 and 5 to these Sanitary Rules.

      28. Health facilities use suture material, which is produced in sterile form. The handling and storing of suture material in ethyl alcohol is not allowed.

      29. When preparing anesthetic and respiratory devices for use, special bacterial filters shall be used to equip the specified devices. Bacterial filters are installed and replaced in accordance with instructions for use of a specific bacterial filter. Sterile distilled water is used to fill humidifier tanks. Removable parts of the devices are disinfected in the same way as MDs from relevant materials.

      30. Patient-care items are disinfected as follows:

      1) using the method of wiping with a textile napkin moistened with a disinfectant solution;

      2) using the method of immersion in a disinfectant solution followed by water flushing;

      3) it is possible to use disinfecting pressure washers allowed for use in the prescribed manner.

      31. MDs are sterilized using the chemical treatment method (by immersion in solutions of sterilizing agents), plasma method (based on hydrogen peroxide), steam method (by exposure to pressurized saturated steam), air sterilization (with dry hot air) specified in Appendix 6 to these Sanitary Rules.

      32. The quality of MDs’ sterilization shall be assessed in accordance with Appendix 7 to these Sanitary Rules.

      33. When carrying out disinfection, pre-sterilization cleaning and sterilization with chemical solutions, MDs are immersed in a working solution of a disinfectant (hereinafter referred to as a solution) with channels and cavities to be filled. Detachable devices shall be disassembled before immersion, tools with lock parts shall be soaked open, making several working motions with these tools in a solution.

      34. The volume of a treatment solution must be sufficient to ensure complete immersion of a MD, and the volume of the solution above the devices must be at least one centimeter (hereinafter referred to as cm).

      35. After disinfection, remnants of a disinfectant shall be washed from reusable MD in accordance with instructions (guidelines) for its use.

      36. The quality of pre-sterilization cleaning of MDs shall be assessed daily. Subject to control: is 1% of each name of items treated per shift in the sterilization department; in case of decentralized treatment - 1% of simultaneously treated items of each name, but not less than three units, indicating the dates of sampling, the name and number of treated devices, the number of checked devices, the result of the test, the last and first names and patronymic of the person who did the tests.

      37. Subject to sterilization are MDs in contact with the wound surface, blood (in the patient’s body or injected into it) and (or) injection drugs, as well as certain types of medical instruments that come in contact with the mucous membrane in the course of a surgery or cause damage to it.

      38. MDs, parts of instruments, devices made of corrosion-resistant metals, glass, linen, dressing material, cotton balls, rubber products, latex and certain types of plastics shall be sterilized using the steam method.

      39. The air sterilization method is used for sterilizing MDs, parts of instruments and devices, including those made of non-corrosive metals, silicone rubber products. Before air sterilization, MDs after pre-sterilization cleaning are dried in a drying cabinet at a temperature of 85 degrees Celsius (hereinafter referred to as °C) until visible moisture disappears. Drying cabinets are not used for air sterilization.

      40. The chemical method of sterilization with solutions of chemical agents is used to sterilize devices constructed from thermolabile materials not allowing the use of other sterilization methods. In order to avoid the dilution of working solutions, it is necessary to immerse dry MDs in them. During sterilization with solutions of chemical agents, all manipulations shall be carried out in strict accordance of the following aseptic rules: it is necessary to use sterile sterilization containers and sterile water to wash chemical residues from devices.

      41. The plasma method, using sterilizing agents based on hydrogen peroxide in plasma sterilizers, is used to sterilize surgical, endoscopic instruments, endoscopes, optical devices and appliances, fiber optic light guide cables, probes and sensors, conductive cords and cables, other devices made of metals, latex, plastics, glass and silicon.

      42. Glasperlen sterilizers are used in dental clinics (offices) to sterilize burs and small instruments that shall be fully immersed in heated glass beads. Glasperlen sterilizers are not used to sterilize the working parts of larger dental instruments that cannot be fully immersed in heated glass beads.

      43. Dental instruments made of metal are sterilized by the infrared method. The gas method is used to sterilize devices from various materials, including thermolabile ones, using ethylene oxide, formaldehyde, ozone as sterilizing agents. Before sterilization by the gas method, visible moisture shall be removed from devices after pre-sterilization cleaning.

      44. When using the steam, gas, air and plasma methods, devices are sterilized in a packaged form using paper, combined and plastic sterilization packing materials, as well as parchment and calico (depending on the sterilization method and instructions for their use). Sterilization is carried out in accordance with the modes of use of the means for sterilization of specific groups of devices, and also according to instructions for sterilizers’ use.

      45. When using the steam method, it is also necessary to use sterilization boxes with filters. In case of using the air and infrared methods, instruments can be sterilized unpackaged (on open trays), after which they are immediately used for their intended purpose.

      46. All dental offices are provided with medical equipment and medical devices in an amount sufficient for smooth operation with account of the time required for their treatment between manipulations with patients: for each workplace of a dentist - at least 6 handpieces (of which two are angle, two are straight, two are turbine ones), for each visit - an individual dental examination kit consisting of a set of instruments (tray, dental mirror, dental tweezers, dental probe), a pack with cotton rolls, a pack with a pair of tweezers (to work with sterile instruments needed for each patient), each local anesthesia – a sterile carpool syringe with disposable needle.

      47. Devices sterilized in packaged form are stored in cabinets, on work tables. Storage periods are indicated on the package and determined by the type of packing material according to instructions for its use.

      48. Sterilization of devices in unpackaged form is allowed only with a decentralized treatment system in such cases as:

      sterilization of MDs with chemical solutions;

      2) in case of sterilization of metal instruments by thermal methods (glasperlen, infrared, air, steam) in portable sterilizers. All devices sterilized unpackaged shall be used immediately for their intended purpose. It is not allowed to take them from one office to another.

      49. Instruments sterilized in unpackaged form using one of the thermal methods, after sterilization, may be stored in germicidal (equipped with ultraviolet lamps) chambers for a period specified in an equipment manual, and in case of no such chambers - on a sterile table for not more than 6 hours.

      50. MDs sterilized in sterilization boxes may be used within 6 hours of their opening.

      51. Bactericidal chambers equipped with ultraviolet lamps are used only for the purpose of storing instruments to reduce the risk of their secondary contamination by microorganisms in accordance with an instruction manual. Such equipment is not used to disinfect or sterilize devices.

      52. When sterilizing by the chemical method using chemical solutions, sterilized devices washed with sterile water shall be used immediately for their intended purpose or stored in a sterile sterilization filter box lined with a sterile sheet for a period not exceeding 3 days.

      53. Prior to covering a sterile table, treatment and procedure rooms are subjected to routine cleaning, bactericidal irradiators are turned on for the estimated time in accordance with the equipment instruction manual. All manipulations on covering a sterile table are carried out in a sterile dressing gown, mask and gloves, using sterile sheets. It is necessary to mark the date and time of covering a sterile table. A sterile table is covered for 6 hours. Materials and instruments not used during this time period shall be sent from the sterile table for re-sterilization.

      54. When performing medical manipulations to treat body zones, it is necessary to use sterile cotton or gauze balls moistened with an antiseptic solution or sterile disposable antiseptic wipes. After sterilization, the use of sterilized MDs with expired shelf life is not allowed.

      55. The assessment of sterilization includes the correct operation of sterilizers, the check of values ​​of the parameters of sterilization modes and evaluation of its efficiency. Sterilizers’ operation is tested by physical (using instrumentation), chemical (using chemical indicators) and bacteriological (using biological indicators) methods. The parameters of sterilization modes are controlled by physical and chemical methods.

      The sterilization efficiency is assessed based on the results of bacteriological studies while monitoring the sterility of MDs.

      56. Sterilizers are subject to bacteriological control after their installation (repair), as well as during operation at least twice a year in the course of operational control.

      57. Sterilizers’ maintenance, warranty and current repairs shall be carried out by service technicians.

      58. The operation of steam and air sterilizers is assessed by physical, chemical and bacteriological methods using chemical and biological tests, thermochemical indicators.

      59. The physical and chemical methods are used to evaluate the operating parameters of steam and air sterilizers during the sterilization cycle, using the bacteriological method to evaluate the sterilizer’s efficiency.

      60. Sterilizers’ operation is assessed by specialists of a health facility every time a sterilizer is loaded.

      61. Measuring instruments for sterilization equipment are subject to verification in the manner established by the Law of the Republic of Kazakhstan “On Ensuring the Uniformity of Measurements” as of June 7, 2000.

      62. Sterilizers’ efficiency shall be checked by territorial divisions of the department of the state body in the field of the sanitary and epidemiological welfare of the population.

      63. When testing the sterilizer’s temperature, tests (chemical tests, thermochemical indicators and biological tests) shall be packaged in bags of packing paper with a sterilized material and placed according to control points and the formulation of chemical tests to check the temperature parameters of the steam and air sterilizers specified in Appendix 8 to these Sanitary Rules.

      64. Each batch of sterilized material is recorded in a log indicating the brand, sterilizer number, sterilization time, sterilization mode, test-control results. The sterilizer passport, certificates, reports of inspection of sterilizers’ technical condition and sterilization’s efficiency are stored by an authorized person at health facilities.

      65. Endoscopes used for non-sterile endoscopic manipulations (introduction of endoscopes through natural pathways having their own microbial landscape into a body cavity), immediately after their use, are subject to preliminary cleaning, final cleaning, high-level disinfection and storage under conditions excluding secondary contamination by microorganisms.

      Endoscopes used in sterile endoscopic procedures (introduction of sterile instruments used in surgical interventions through their channels, introduction of endoscopes into sterile cavities, contact with the wound surface, blood), immediately after their use, must be pre-cleaned, pre-sterilized, sterilized and stored under conditions excluding secondary contamination by microorganisms.

      Disinfection, pre-sterilization cleaning and sterilization of endoscopes and their instruments are carried out in accordance with Appendix 9 to these Sanitary Rules.

      66. Responsibility for the organization, quality of sterilization and disinfection of MDs rests with heads of health facilities.

      67. The physical method of monitoring sterilizers’ operation employs the means of measuring temperature (thermometer, maximum thermometer), pressure (pressure gauge) and sterilization time. The operating mode parameters of the sterilizer are checked during the entire cycle of sterilization, which is carried out in accordance with the device passport.

      68. The chemical control method employs chemical tests and thermochemical indicators. The change of indicators’ color visually shows the end of sterilization.

      69. The bacteriological control method employs biological tests containing a metered amount of microbial spores. Biological tests are prepared by bacteriological laboratories having a permit from the regime commission for the work with microorganisms of groups I-IV pathogenicity.

      70. After sterilization is completed, biological tests are placed in a plastic bag and on the same day are delivered to a bacteriological laboratory for sanitary-microbiological examination.

      71. Steam sterilizers can only be operated by persons over eighteen years of age, after they are trained in safety requirements to be observed when operating a steam sterilizer.

      72. A steam sterilizer is installed at a distance of 0.8 meters (hereinafter referred to as m) from walls, cabinet sterilizers - at a distance of 1.5 m. The floor in a room shall be covered with a non-conductive material.

      73. Each electric sterilizer is connected to the mains through a switch or a circuit breaker. The switch or circuit breaker shall be installed at a distance of 1.6 m from the floor and not farther than 1 m from the steam sterilizer. Other consumers of electricity may not be connected to this switch or circuit breaker.

      74. Water pipes of a central heating network, sewage system, pipelines of combustible or explosive substances, earthing switches of lightning rods may not be used as earthing.

      75. Sterilizers may only be used for sterilization of medical devices, and it is not allowed storing in a room alien items cluttering and contaminating it.

      76. Entry into a room with operating sterilizers is allowed only to service personnel and persons supervising the sterilizers’ operation.

      77. In each room with installed sterilization equipment, rules for its operation shall be in a prominent place.

      78. The autoclave room shall have daylight, forced-air ventilation, transom or vent windows. During the sterilizer’s operation, the room’s door shall not be locked.

      79. Each steam sterilizer shall be equipped with a safety valve and a serviceable sealed pressure gauge having an accuracy class of at least two and a half and such a scale so that the limit of measurement of the working pressure is in the second third of the scale.

      80. A pressure gauge is not allowed to be used in case of no seal on the stamp, overdue period of verification, broken glass or other damage.

      81. The service personnel fulfill the requirements for the operation mode and safe maintenance of steam sterilizers, timely check the operability of instrumentation and safety devices.

      Chapter 4. Sanitary and epidemiological requirements for the organization and conduct of pest control

      82. To begin pest control at facilities, it is necessary to check the presence of insects there, identify their species, the places of their colonization and their number.

      83. An indicator of efficiency of performed pest control is the increase of a pest-free area, and in case of flies’ extermination - the absence of larvae, pupae and their reduced number.

      84. Pest control is carried out in industrial, residential premises, buildings, structures, transport, in urban and rural settlements, adjacent areas of nature, including water bodies, as well as natural habitats of synanthropic arthropods and rodents.

      85. To control bloodsucking insects, the following types of pest control are used:

      1) environmental – support of appropriate sanitary state of the environment to prevent their reproduction;

      hydrotechnical - drainage of bogs, reconstruction of irrigation systems;

      3) biological – the use of bacterial preparations, larvivorous fish (larvaephagous species);

      physical - the use of petroleum products, fats and others;

      5) chemical - the use of chemically synthesized substances.

      86. Three types of pest control are applied against insects and other arthropods:

      1) general treatment – it is carried out in all the rooms inhabited by the target insect species and in adjacent areas;

      2) barrier treatment - the creation of protective zones around a certain area;

      3) microfocal treatment – pest control in a focus of infectious diseases and in adjacent area.

      87. Before a large-scale application of an insecticide, it is preliminarily tested (pilot test) in local conditions in order to fix minimum dosages, which give required effect, with account of climatic conditions.

      88. Time frames for preventive treatments are set based on the specific nature of local conditions and the data of entomological monitoring. The frequency of treatments against insects (cockroaches, flies, ants, bugs, fleas) depends on the colonization of an object; against flies and mosquitoes (in flooded, damp, wet basements, with a high level of groundwater, in emergency situations in the sewer network) in emergency rooms and recreation areas, it is carried out given sanitary and epidemiological and entomological indications.

      The frequency of pest control at facilities of the food industry, catering and food trade is once a month, at children’s institutions, health facilities, public facilities - once every 3 months and given indications.

      89. An indicator to begin treatments is the outbreak of second-age larvae and first third-age larvae in water bodies. The frequency is determined by the number of restoration of the number of larvae and the period of their activity.

      90. Measures to exterminate the larvae of anopheles mosquitoes are carried out in all anophelogenous reservoirs within the territory of populated localities of the 1st danger level of malaria comeback, as well as within a radius of 3-5 kilometers (hereinafter referred to as km) around them.

      91. Treatments against blackflies are carried out in case of the outbreak of middle-aged larvae. In those places where black flies have one generation, the number of treatments is limited to 1-2 per season; in the presence of two or more generations - 4 treatments and more. Examination of water bodies to be treated and entomological examinations are carried out once every 5-10 days.

      92. An object is classified as “pest-free” if no insects have been seen for a month in any of the premises. If even few live insects are found, the object shall be re-classified as “colonized” and re-treated. The insect colonization of buildings (or in-built objects) is considered high if separate insects and their clusters are found in more than 20% of the area of ​​the object. In this case, general treatment is mandatory.

      93. If treatments are found to have been useless, they shall be repeated at the expense of the contractor.

      94. The treatment against mosquitoes is carried out immediately before their departure from wintering grounds or before the departure of the first generation, in heated basements the treatment shall be carried out year-round.

      95. The main measure in flies’ extermination is the treatment of their hatching sites. To exterminate larvae and pupae of flies, the soil is treated with larvicides at a distance of 30-50 cm and more up to 80 cm from the edges of garbage collectors, outside lavatories, asphalt platforms surrounding outdoor sanitary facilities, manure accumulations.

      96. Regular antilarval (against larvae and pupae of flies) works begin in the spring after the appearance of larvae of stages I and II of the first summer generation and continue throughout the summer period. To exterminate the larvae and pupae of flies in garbage, manure and soil, insecticides shall be used in the form of solutions, emulsions for better penetration into the treated substrate.

      97. When treating open areas against exophilous species, components of gnats, antilarval treatment of all coastal reservoirs, places of mass hatching shall be carried out both within the territory of the protected object (a populated locality, place of work of a large group of people) and around it (a protective zone). The width of the protective zone, depending on the landscape, plant colonization, the range of expansion of gnats shall have a radius of 1-6 km and more.

      98. The criterion for evaluating the efficiency of performed anti-fly measures is a seasonal indicator of the number of indoor and exophilous species of flies.

      99. Flies are counted once every 3-10 days within 24 hours during the activity period of flies, in the premises flies are counted with the help of sticky paper - 1 sheet per 20 square meters (hereinafter referred to as m2), at hatching sites, they are caught with netlike flycatchers. Efficiency is considered to be satisfactory in case of absence of winged flies, with an average number of no more than 1 specimen per 1 standard sticky sheet (per day). For areas mainly built with private houses without sewage pipes and for rural areas - 3-5 sheets.

      100. The efficiency of actions is measured by counting the number of winged flies, as well as larvae and pupae at hatching sites. Flies shall be counted in at least 5% of serviced objects in a populated locality.

      101. Pest control measures are stopped if, within a month after treatments, no insects have been found in the course of controls conducted by all methods.

      102. The efficiency of pest control measures against mosquitoes at sites is determined within a period specified by a disinfectant used, the type of treated surfaces. Mosquitoes are counted within 20 minutes using the “open palm technique”.

      103. The main indicator of efficiency of antilarval measures is the number of winged mosquitoes in protected objects; in case of detection of the larvae and imago mosquitoes 5–7 days after the treatment, not more than 1 winged mosquito per 1 m2 of basement is considered to be acceptable.

      104. The criterion for evaluating the efficiency of anti-gnat and anti-tick measures in open areas, the treatment of rodent burrows during the creation of protective zones is the death of at least 80% of insects (ticks) a day after the treatment of 100% of the area subject to pest control.

      105. The indicator of the efficiency of pest control of basement mosquitoes is the absence, 3-5 days after the treatment, of live larvae in samples and the presence, on the average, of no more than 1 winged mosquito per 10 m2.

      106. When assessing the efficiency of measures for the extermination of fleas in the premises, it is necessary to use sticky sheets (20x30 cm) - 2 sheets per 10 m2 of floor surface. If no more than 2 fleas were caught by a sheet, insects are considered to be “few”, from 3 to 10 - “many fleas”, more than 10 - “a great many”.

      107. When assessing the efficiency of measures for the extermination of bed bugs, their most probable locations shall be examined, the results of the inspection are recorded as follows: “few insects”, “cluster of insects”, and in the absence of bugs - “insects were not found”.

      108. When evaluating the efficiency of anti-lice measures, it is considered to be satisfactory in case of no insects and nits found after treatment.

      Chapter 5. Sanitary and epidemiological requirements for the organization and conduct of rodent control

      109. Rodent control aims at exterminating rodents and freeing populated localities from them or keeping their number at a minimum level, ensuring the prevention of wide spread of infectious diseases and substantial economic damage.

      110. Rodent control is divided into such types as:

      1) general rodent control – it is carried out throughout the entire populated locality, including open habitats within it, at least 2 times a year;

      2) focal rodent control – rodent control in a focus of infectious diseases and in adjacent area. It is carried out in case of registration of an infectious disease, which may be communicated by rodents;

      3) selective rodent control – it is carried out during the extermination of rodents in certain areas or buildings, at epidemically significant facilities: meat and fish factories, refrigerators, elevators, food warehouses, in health and childcare facilities, on livestock farms.

      111. Rodent control is carried out using physical, mechanical, chemical methods, methods of laying poisoned baits, dusting, aeration. The choice of the way and method of rodent control is determined by peculiarities of an object under treatment, the ecology of target rodents and properties of rodenticides.

      112. Barrier rodent control is carried out during periods of the greatest migratory activity of rodents, and at sites of special epidemiological importance - all year round by placing control and destructive sites (hereinafter referred to as CDS) around the perimeter of the territory (every 20 m along the fence), buildings (every 10 m along the blind area) and on undeveloped plots (1 CDS per 100 m2). CDSs are placed ensuring the safety of humans.

      113. It is mandatory to check whether there are rodents in the entire area of ​​buildings and territories of health facilities, educational institutions, educational institutions for orphaned children, children without parental care, catering and food trade facilities.

      114. To ensure the efficiency of prophylactic rodent control, treatments shall be conducted a certain number of times. If instructions for the preparation’s use do not recommend otherwise, the rodent control of premises shall be carried out once every 2-3 months, the rodent control of the territory - 4-6 times a year. If there are no rodents for a long time in the premises, the latter are excluded from the treatment plan, and the number of treatments of the territory shall be halved. In case of dense colonization of rodents, the frequency of treatments increases to once a month.

      115. A poisoned bait at facilities of food trade, public catering, vegetable storehouses, warehouses, residential premises and outbuildings is laid out in accordance with the mode of use provided for in the instructions for rodenticides’ use. In the premises of children’s institutions, to which children have access, it is not allowed to lay out the poisoned bait, and rodents are exterminated using solely mechanical methods.

      116. It is not allowed to use whole sunflower seeds and other products, looking attractive for people, as a food base for baits. In order to avoid accidents, rodent bait for rodents shall have a bright color.

      117. Poisoned bait in open areas is laid out only secretly in places inaccessible to people, domestic animals and birds.

      118. Poisoned baits shall be prepared in specially equipped rooms (laboratories) and their preparation shall be mechanized to the maximum possible extent using special mixers. Poisoned baits are prepared and packed under an exhaust hood and with observance of security measures specified in relevant instructions for specific rodenticides. In the working premises for preparing baits, it is necessary to take regular air samples for the presence of the rodenticide’s active ingredient.

      119. In the premises with unpacked food products, it is prohibited to use dry poisoned baits.

      120. In the premises occupied by people, after the completion of rodent control, all the remains of bait with poison are collected for their disposal. In places inaccessible to children and pets, the bait is left to prevent rodents from entering the protected object.

      121. The efficiency of rodent control is achieved by:

      1) organizing a cleanup day at an object to conduct a general treatment of all rooms inhabited by rodents;

      2) observing the bait layout technology provided for in the instructions for its use;

      3) providing in warehouses constant access to walls, corners and technical inputs for persons conducting rodent control by arranging a passage of at least 70 cm wide along walls;

      4) making racks at least 15 cm above the floor in all places of storage of various materials;

      5) storing food and water supplies to hinder access to them for rodents;

      6) providing access for persons conducting rodent control to all premises for preventive treatment before they are loaded;

      7) observing the rules of rodent impermeability of buildings and premises;

      8) regular cleaning of all premises and adjacent territory and taking out the garbage on time.

      122. In case of general rodent control in a populated locality, its population shall be notified thereof through mass media 24 hours before the start of rodent control.

      123. A populated locality or its part is divided into sections, which are numbered and plotted on a schematic map. The size of a section is determined based on the amount of works. Each section is assigned to a specific rodent exterminator.

      124. In the event of the onset of an infectious disease associated with rodents, rodent control is carried out according to the type of emergency prophylaxis: acutely active rodenticides as part of poisoned food baits are used. A mixture of grain (wheat or corn) with attractants (vegetable oil, sugar) is used as a bait base. 3 weight parts of attractants are added to 100 weight parts of grain.

      125. The basic principle of the most efficient method of killing synanthropic rodents is the use of means of extermination in all habitats of rodents, without exception, and the continuity of this effect.

      126. As the main means of control, long keeping baits with anticoagulants are used, and baits with acutely active poisons - no more than twice a year during the autumn peak of the number and spring breeding of rodents, as well as given epidemiological indications.

      127. It is recommended to use rate mashers, traps and other catchers in separate objects as an additional method of rodent control.

      128. The dosage of the preparation for dusting holes and trails of rodents is calculated in an acceptable dosage in accordance with the instructions, in order to prevent the pollution of the environment by pesticides and the danger of works for persons who are constantly present in the treated room.

      129. An important condition for good-quality rodent control is the use of various products attractive for rodents in poison baits: flour, grain, cereals, sugar, vegetable oil, less often bread, vegetables, meat and fish waste.

      130. The indicator of the quality of rodent control is the count of the number of rodents, which is carried out according to Appendix 10 to these Sanitary Rules.

      131. Rodent control in a populated locality is recognized as efficient in case of death of at least 80% of rodents.

      Chapter 6. Sanitary and epidemiological requirements for individuals and legal entities providing services of disinfection, pest and rodent control

      132. Disinfectants, insecticides and rodenticides are manufactured in a separate building, separately in different rooms, poisoned baits are prepared in a separate, isolated room of the building.

      133. Production and storage facilities are equipped with appropriate processing equipment, racks, shelves, cabinets, the surfaces of which allow for easy cleaning and disinfection.

      134. A chemical resistant coating is used in the flooring of industrial facilities. The finishing of walls, ceilings and surfaces of structures shall allow for wet cleaning.

      135. Workrooms for the preparation of disinfectants, insecticides and rodenticides are equipped with plumbing, sewage, are connected to the power supply and equipped with supply and exhaust ventilation.

      136. Works on the preparation of working solutions of disinfectants, insecticides and rodenticides, their spraying, production, packaging are carried out in a special room equipped with supply and exhaust ventilation, with the obligatory use of special clothes (hereinafter referred to as work clothes) and personal protective equipment (suits, gloves, headwear, respirators). When treating the premises, the operator must leave the treated area every 40 minutes or go outdoors for 10-15 minutes. Access to these rooms is prohibited to unauthorized persons, as well as the storage of personal belongings, food, eating, smoking.

      137. Heads of individuals and legal entities engaged in the production of disinfectants, insecticides and rodenticides or providing services of disinfection, pest and rodent control shall ensure:

      1) the observance of measures of individual and public safety in the course of disinfection activity;

      2) implementation of production control, also through laboratory studies and testing;

      3) timely informing of the population, the territorial subdivision of the department of the state body in the field of sanitary and epidemiological welfare of the population on emergencies or process disruptions that pose a threat to public health.

      138. The personnel room shall be equipped with a shower and a toilet, lockers for separate storage of work and personal clothes, equipped with a first-aid kit and personal protective equipment and personal hygiene products.

      139. Laboratories and premises for storage and distribution of disinfectants are provided with supply and exhaust ventilation.

      140. Work clothes are washed, disinfected in a specially equipped room; washing at home and at work is not allowed.

      141. Disinfection, pest and rodent control events at objects are carried out in the presence of a representative of the object’s authorities (customer). Persons in the premises to be treated shall be notified in advance of the events and necessary precautions. Persons not involved in the treatment, as well as pets, are not allowed to be in the areas to be treated.

|  |  |
| --- | --- |
|   | Appendix 1 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Hazard classification of disinfectants, insecticides, rodenticides**
**1. Hazard classification of disinfectants Table №1**

|  |  |  |
| --- | --- | --- |
|
Hazard class  |
Zone of acute toxicity: the ratio of the threshold of acute action to the rate of consumption  |
Recommended conditions of use |
|
class 1 - extremely hazardous |
Under 1 |
Used in extreme situations (given epidemiological indications) in special suits and gas masks |
|
class 2 – highly hazardous |
1-3 |
Used in the absence of people with the use of respiratory, eye, skin protection equipment  |
|
class 3 – moderately hazardous |
3,1-10 |
Used without respiratory and eye protection equipment, but in the absence of people  |
|
class 4 – low-hazard |
Over 10 |
Used without limiting the scope of application  |

 **2. Hazard classification of insecticides Table №2**

|  |  |  |
| --- | --- | --- |
|
Hazard class |
Zone of biocidal action |
Opinion on the possibility and scope of use of preparations for disinfection |
|
acute |
sub-acute |
|
consumption rate  |
consumption rate |
|
class 1 - extremely hazardous |
< 10 |
< 1 |
Not recommended for use |
|
class 2 – highly hazardous |
10-30 |
1-5 |
Recommended for use only by professional personnel with respiratory, eyes, skin protection equipment, in the absence of people with controlled conditions of use (consumption of a preparation, ventilation and wet cleaning)  |
|
class 3 – moderately hazardous |
31-100 |
5,1-10 |
Recommended for use by professional personnel and people in everyday life with controlled conditions of use (consumption of preparations, ventilation regime, cleaning) in any type of premises  |
|
class 4 – low-hazard |
> 100 |
> 10 |
Used without limiting the scope of application |

 **3. Hazard classification of rodenticides**

      Table №3

|  |  |  |
| --- | --- | --- |
|
Limiting properties  |
Indicators  |
Hazard classes  |
|
class 1 - extremely hazardous |
class 2 – highly hazardous |
class 3 – moderately hazardous |
class 4 – low-hazard |
|
"A" |
"B" |
|
Acute toxicity (for potentially hazardous airways) |
LD50 when injected into the stomach, mg/kg |
< 2 |
2,1-14 |
15-150 |
151-5000 |
>5000 |
|
ТL50 |
< 1 |
>1 |
>1 |
>1 |
>1 |
|
Antidote  |
- |
+ |
+ |
+ |
+ |
|
LD50 when applied to the skin, mg/kg |
< 100 |
100-500 |
501-2500 |
>2500 |
|
LD50 when inhaled, mg/kg |
< 500 |
500-5000 |
5001-50000 |
>50000 |
|
С20 (by degree of volatility) for fumigants  |
Severe poisoning with possible death  |
Poisoning above the threshold of acute action |
Poisoning at the threshold of acute action |
No poisoning  |
|
Selective toxicity (ST) |
LD50 for non-target species of animals (cat, dog, pig, chicken)
LD50 for target species of animals (rodents)  |
< 3 |
3,1-2 |
9,1-37 |
>27 |
|
Cumulative effect  |
LD50nCcum= ----- LD501 |
< 1 |
1-3 |
3,5-5 |
>5 |
|
Stability (soil) |
Time of degradation into non-toxic components (T1/2), months |
>12 |
6-12 |
1-6,1 |
< 1 |

      Note:

      (+) – the presence of an antidote;

      (-) – the absence of an antidote;

      LD50 – an average lethal dose;

      ТL50 – a time period running from the moment of experimental treatment, within which 50% of animals died;

      С20 – the concentration of the substance’s vapor in the air at a temperature of 20 degrees Celsius;

      Ccum – cumulative coefficient;

      LD50n – an average lethal dose after a cumulative dose;

      LD501 – an average lethal dose after a single dose;

      Т1/2 – half-life period.

      Appendix 2 to Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control”

      Rates for planning disinfectant consumption when disinfecting individual items

      Table №1

|  |  |  |  |
| --- | --- | --- | --- |
|
Items to be decontaminated |
Unit of measurement |
Average amount of disinfectant |
Note |
|
Surface in residential premises |
1 m2 |
As prescribed by instructions (guidelines) for the use of a preparation |
In an anthrax focus, the rate is 2 liters in case of double treatment |
|
Linen  |
1 kg |
4 – 5 liters of a working solution  |  |
|
Kitchenware and other |
1 set |
2 – 3 liters of a working solution  |  |
|
Soil surface, garbage |
1 m2 |
2 liters of a working solution  |
In case of an anthrax, 8 – 10 liters  |
|
Discharges  |
1 kg or l л |
As prescribed by instructions (guidelines) for the use of a preparation |
In case of an anthrax, 0.5 liters  |
|
Leftover food |
1kg |
0.1 kg |  |

      Note: A set of kitchenware includes: 2 plates, a glass and a cup and saucer, 2 spoons, a fork and a knife.

      Table №2

|  |  |
| --- | --- |
|
Item |
Average volume of work for basic objects to be decontaminated |
|
Premises in m2 |
Linen in kilograms (hereinafter referred to as kg) |
Kitchenware sets |
Bedding in kg |
|
Home |
200 |
5 |
3 |
30 |
|
Organized team (an educational institution, a home for the elderly, disabled, etc.) |
450 |
50 |
50 |
100 |

      Note:

      1. To plan the consumption of disinfectants for disinfecting foci, the below indicated formula shall be used:

      X = Q х (Х1 + Х2 + Х3 + Х4 + Х5), where

      Х – annual demand for disinfectants (in kilograms or liters);

      Q – number of disinfections (average number of disinfections over previous two years);

      Х1 – demand for disinfectants to disinfect surfaces;

      Х2 – demand for disinfectants to disinfect linen;

      Х3 – demand for disinfectants to disinfect discharges;

      Х4 – demand for disinfectants to disinfect leftover food;

      Х5 – demand for disinfectants to disinfect kitchenware;

      1) to calculate the demand for disinfectants to disinfect surfaces, the below indicated formula shall be used:

      Х1 = 0.01 х ((N1 х К х (S1 + S2 +S3), where

      N1 – the consumption rate of a disinfectant per square meter (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      К1 – the concentration of a disinfecting solution in a preparation in accordance with instructions (guidelines, recommendations) for the use of a preparation (%);

      S1 – the area of premises to be disinfected (in square meters);

      S2 – the area of equipment to be disinfected (in square meters);

      S3 – the area of other items to be disinfected (in square meters);

      2) to calculate the consumption of disinfectants to disinfect linen, the below indicated formula shall be used:

      Х2 = 0.01 х N2 х К2 х B, where

      N2 – the rate of consumption of a disinfectant per kilogram of linen (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      К2 – the concentration of a disinfecting solution in a preparation in accordance with instructions (guidelines, recommendations) for the use of a preparation (%);

      B – the amount of linen to be disinfected (in kilograms);

      3) to calculate the consumption of disinfectants to disinfect discharges, the below indicated formula shall be used:

      Х3 = 0.01 х N3 х К3 х V, where

      N3 – the consumption rate of a disinfectant per one kilogram or liter of discharges (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      К3 – the concentration of a disinfecting solution in a preparation in accordance with instructions (guidelines, recommendations) for the use of a preparation (%);

      V – the amount of discharges to be disinfected (in kilograms or liters);

      4) to calculate the consumption of disinfectants to disinfect leftover food, the below indicated formula shall be used:

      Х4 = 0.01 х N4 х К4 х O, where

      N4 – the consumption rate of a disinfectant per one kilogram or liter of leftover food (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      К4 – the concentration of a disinfecting solution in a preparation in accordance with instructions (guidelines, recommendations) for the use of a preparation (%);

      O – the amount of leftover food to be disinfected (in kilograms or liters);

      5) to calculate the consumption of disinfectants to disinfect kitchenware, the below indicated formula shall be used:

      Х5 = 0.01 х N5 х К5 х P, where

      N5 – the consumption rate of a disinfectant per one set of kitchenware (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      К5 – the concentration of a disinfecting solution in a preparation in accordance with instructions (guidelines, recommendations) for the use of a preparation (%);

      P – the number of sets to be disinfected (sets).

      2. To calculate the demand for insecticides for pest control, the below indicated formula shall be used:

      Х6 = N6 х S6, where

      Х6 – the demand for insecticides for pest control;

      N6 – the consumption rate of an insecticide per one square meter (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      S6 – the area subject to pest control (in square meters).

      3. To calculate the demand for rodenticides for rodent control, the below indicated formula shall be used:

      Х7 = N7 х S7, where

      Х6 – the demand for rodenticides for rodent control;

      N7 – the consumption rate of a disinfectant per one square meter (in accordance with instructions (guidelines, recommendations) for the use of a preparation);

      S7 – the area subject to rodent control (in square meters).

      Appendix 3 to Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control”

      Calculation of health facilities’ need for disinfectants

      1. For current disinfection of premises, equipment, the below indicated formula for calculating health facilities’ needs for disinfectants shall be used:

      NK X1 = Q ---------- (S1 + S2 + S3), where 100

      Х1 – annual need of a facility for disinfectants (in kilograms or liters);

      Q – the number of disinfections (based on the number of working days and frequency of disinfections);

      N – the consumption rate of a disinfectant (one square meter per liter);

      K – the concentration of a disinfecting solution (%);

      S1 – the area to be disinfected (in square meters);

      S2 – the area of equipment to be disinfected (the area of ​​each unit of sanitary equipment is taken as one square meter, of a bathtub - three square meters);

      S3 – the area of other objects to be disinfected (in square meters).

      2. For final disinfection in medical treatment, dressing, operating rooms, delivery rooms, the below indicated formula for calculating health facilities’ need for disinfectants shall be used:

      NK Х2 = 52 ---------- S4, where 100

      Х2 - the facility’s annual need for disinfectants for overall cleaning;

      52 – the number of overall cleanings (given one cleaning per week);

      N - the consumption rate of a disinfectant per one square meter;

      K - the concentration of a disinfecting solution;

      S4 - operational area subject to overall cleaning.

      3. To provide health facilities with disinfection and sterilization equipment, the below indicated calculation of the need shall be used:

      1) needs for disinfection and sterilization equipment (autoclaves, mechanical and ultrasonic washers, dressing sterilizers) are determined on the basis of the volume of soft material (dressing) to be sterilized, surgical drapes, diapers, medical instruments, products with an appropriate sterilization mode;

      2) two thirds of the volume of dressing sterilizers and autoclaves, sterilizers shall be filled. Homogeneous material shall be laid in dressing sterilizers;

      4) the frequency of laying materials (dressing sterilizers) in autoclaves shall not be more than 5 (five) times a day, in dry-air sterilizers - not more than 8 (eight) times;

      5) the amount of equipment units is determined on the basis of the volume of loads made per number of loads per shift;

      6) the number of dressing boxes for type 1 sterilizers shall not be not more than 20 dressing sterilizers per shift, for type 2 sterilizers with a single laying of 5-8 dressing sterilizers - not more than 40 dressing sterilizers per shift, for type 3 sterilizers - 25 dressing sterilizers per shift, for type 4 sterilizers - 65 dressing sterilizers.

|  |  |
| --- | --- |
|   | Appendix 4 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Disinfection of medical devices**

|  |  |  |  |
| --- | --- | --- | --- |
|
Method of disinfection  |
Mode of disinfection  |
Applied to |
Conditions of disinfection  |
|
Temperature in degrees Celsius (hereinafter referred to as оС) |
Concentration in percentage terms (hereinafter referred to as %) |
Time of disinfection, in minutes |
|
Boiling: in distilled water; distilled water plus sodium bicarbonate (baking soda) |
98 |
2.0 |
30
15 |
For products made of glass, metal, heat-resistant polymeric materials, rubber |
Full immersion in water  |
|
Steam: held in a steam sterilizer or disinfection chamber  |
110 |  |
20 |
For products made of glass, metal, rubber, latex, heat-resistant polymers |
Laid in dressing boxes |
|
Air: held in an air sterilizer with dry hot air  |
120 |  |
45 |
For products made of glass and metal |
Carried out on trays without packing  |
|
Chemical: held in a container made of glass, plastic or in an enamel container  |
In accordance with the instructions (guidelines) for the use of a preparation |
For products made of glass, corrosion-resistant materials of polymeric materials, rubber |
Full immersion in a solution |

      Note: after chemical disinfection, products must be washed in running water until the odor of a disinfectant is completely removed; When disinfecting by boiling and the steam method, products made of polymeric materials shall be packed in gauze.

|  |  |
| --- | --- |
|   | Appendix 5 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Pre-sterilization treatment of medical devices**

      Table № 1

|  |  |  |
| --- | --- | --- |
|
Processes of treatment |
Initial temperature of a solution in °C |
Exposure time in minutes |
|
1. After disinfection is over, MDs are rinsed with running water |  |
0.5 |
|
then: they are soaked with full immersion in one of the solutions of a detergent  |
20 – 25 |
15 |
|
2. Washing of each product in a washing solution using a brush or cotton-gauze swab |  |
0.5 |
|
3. Rinsing with running water |  |
10,0 |
|
4. Rinsing with distilled water |  |
0.5 |
|
5. Hot air drying in a hot-air oven  |
85 |
Until moisture completely disappears |

      Table № 2

|  |  |  |
| --- | --- | --- |
|
Preparation of a washing solution |
Number of components for preparation |
Where applied |
|
1. Detergent
Drinking water |
3 grams (hereinafter referred to as gr)
up to 1 liter |
Used for mechanized cleaning (jet method, brushing, use of ultrasound) |
|
2. Detergent
Drinking water |
1.5 gr
up to 1 liter |
Used in mechanized cleaning by rotation method |
|
3. Detergent
Drinking water |
5 gr
up to 1 liter |
Used for manual cleaning |
|
4. Hydrogen peroxide solution 27.5%.
Detergent
Drinking water |
17 gr
5 gr
up to 1 liter |
Used for mechanized cleaning (jet method, brushing, use of ultrasound) and manual cleaning  |
|
5. Detergent 0.8%.
Drinking water
Detergent 1.6 %
Drinking water |
8 milliliter (hereinafter referred to as ml) of concentrate
up to 1 liter
16 ml concentrate
up to 1 liter |
Used for manual cleaning |

|  |  |
| --- | --- |
|   | Appendix 6 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Methods of sterilization of medical devices**
**1. Chemical method of sterilization (chemical solutions)**

      Table № 1

|  |  |  |  |
| --- | --- | --- | --- |
|
Sterilizing agent  |
Sterilization mode (temperature, exposure time) |
Product name |
Conditions of sterilization  |
|
Disinfectant solution  |
In accordance with the instructions (guidelines) for the use of a preparation |
Recommended for products made of polymeric materials, rubber, glass, corrosion-resistant metals |
Carried out with full immersion of a product in a solution, after which the product is washed with sterile water. The shelf life of a sterile product in a sterile container lined with a sterile sheet is 3 days. |

      Note:

      1. The temperature of solutions is not kept up in the course of sterilization.

      2. For immersing products in a disinfecting solution, it is necessary to use containers made of glass, plastic or enameled ones.

      2. Steam method of sterilization (saturated water steam under pressure)

      Table № 2

|  |  |
| --- | --- |
|
Mode of sterilization |
Applied to |
|
Steam pressure in a sterilization chamber in kg/cm2 |
Temperature in a sterilization chamber in °C |
Exposure time, in minutes |
|
Nominal value |
Nominal value |
With manual, semi-automatic and automatic control  |
|
0.20 maximum deviation 0.02
(2.0 deviation plus or minus 0.2) |
132 plus or minus 2 |
20 |
Recommended for products made of corrosion-resistant metals, glass, rubber products |
|
0.11 maximum deviation 0.02
(1.1 deviation - plus or minus 0.2) |
120 plus or minus 2 |
45 |
Recommended for products made of rubber, latex and certain polymeric materials (high density polyethylene, polyvinyl chloride - plastic compounds) |

      Note:

      1. Sterilization is carried out in sterilization boxes without filters or in sterilization boxes with a filter or in a double soft package made of calico or parchment, bag paper, untreated wet-strength bag paper, food packaging paper on E brand machines, crepe paper in steam sterilizers.

      2. The shelf life of products sterilized in filter boxes is twenty days (in an unopened package), and in the rest of the package - three days (in an unopened package).

      3. Air method of sterilization (dry hot air)

      Table № 3

|  |  |
| --- | --- |
|
Mode of sterilization  |
Applied to |
|
Operating temperature in a sterilization chamber in °C
nominal value |
Time of exposure to sterilization in minutes, nominal value  |
|
180 (plus 2; minus 10) |
60 (plus 5) |
Recommended for products made of metal, glass and silicone rubber |
|
160 (plus 2; minus 10) |
150 |

      Note:

      1. Dry products are subject to sterilization. Sterilization is carried out in the packaging of untreated bag paper, wet-strength bag paper, food packaging paper on E brand machines, high-strength packaging paper, crepe paper, two-layer crepe paper or without packaging in an open container in an air sterilizer.

      2. Unpacked sterilized products are used immediately after sterilization, in packaged form - within three days.

|  |  |
| --- | --- |
|   | Appendix 7 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Assessment of the quality of medical devices’ sterilization**

|  |  |  |
| --- | --- | --- |
|
Item №  |
Control over |
Types of control |
|
Self-control conducted by the facility’s staff |
Carried out by the territorial department of the agency of the state body in the field of sanitary and epidemiological welfare of the population |
|
1 |
Sterilization conditions:
Sterilizers’ operation, mode, packaging and loading |
Visual – of each cycle and using tests approved in the Republic of Kazakhstan, monitoring the serviceability of control and measurement instruments (hereinafter referred to as CMI)  |
Visual assessment of sterilizers’ operation at each examination using bacteriological tests, temperature measurement tools. At least 25% of devices, including all devices within a year, are subject to control, and also given indications after installation and repair with reference loading  |
|
2 |
MDs’ sterility |
Bacteriological -
in accordance with rationing documents  |
Bacteriological -
at each examination |
|
3 |
Air in centralized sterilization units  |
Daily - when airing, in the course of operation of ventilation systems, air conditioners, germicidal lamps.
Air sampling -
in accordance with rationing documents  |
Bacteriological -
in a sterile area at each examination  |
|
4 |
The presence of hidden blood and the residue of alkaline components (azopiramic and phenolphthalein tests) |
Daily, 1% of simultaneously treated products, but not less than 3-5 units from each batch  |
Visual assessment at each examination.  |

      Note: when monitoring the sanitary condition of the central sterilization department, at least 10 bacteriological washings shall be collected in the sterile area during each examination. Not more than 1% of the total number of selected washings is allowed for seeding sanitary indicator microflora.

|  |  |
| --- | --- |
|   | Appendix 8 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Location of control points and formulation of chemical tests to control the temperature**
**parameters of the mode of operation of steam and air sterilizers**
**1. Location of control points in steam sterilizers**

      Table № 1

|  |  |  |
| --- | --- | --- |
|
Capacity of a sterilizer chamber in cubic decimeters |
Number of control points |
Location of control points |
|
under 100 |
5 |
For rectangular sterilizers:
one is at the loading door;
two - at the opposite wall (discharge door);
three, four, five - in the center. |
|
over 100 to 750 inclusive |
11 |
For round vertical sterilizers:
one is at the top of the chamber;
two - at the bottom of the chamber;
from three to eleven - in the center.  |
|
over 750 |
13 |
For round horizontal sterilizers:
one is at the loading door;
two - at the opposite wall (discharge door);
from three to thirteen - in the center of dressing boxes or inside sterilized packages placed at different levels. |

 **2. Location of control points in air sterilizers**

      Table № 2

|  |  |  |
| --- | --- | --- |
|
Capacity of a sterilizer chamber in cubic decimeters |
Number of control points |
Location of control points |
|
under 80 |
5 |
the first one is in the center of the chamber;
the second, the third ones - in the lower part of the chamber to the right and to the left of the door;
the fourth, the fifth ones - in the lower part of the chamber at the back wall to the left and to the right.  |
|
over 80 |
15 |
the first, the second, the third ones - in the center of the chamber on three levels from top to bottom;
from the fourth to the fifteenth ones - in the corners on three levels (from the fourth to the seventh ones - the bottom; from the eighth to the eleventh ones - the middle; from the twelfth to the fifteenth ones - the top) placing counterclockwise.  |
|
over 80 two-chamber  |
30 |
The same way for each chamber |

      Note: control tests are placed at a distance of at least five centimeters from the sterilizer’s walls.

      Appendix 9 to Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control”

      Requirements for the cycle of treatment of endoscopes and their instruments

      When used, endoscopes contact with mucous membranes and penetrate into sterile organs, tissues and cavities of the body. By their intended purpose, they are divided into endoscopes for non-sterile and sterile endoscopic interventions.

      The sequence of treatment stages of endoscopes used for non-sterile endoscopic manipulations (introduction of endoscopes through natural tracts into the body cavities having their own microbial landscape) and their accessories (valves, plugs, caps) immediately after their use is as follows:

      pre-cleaning;

      final cleaning (final cleaning combined with disinfection);

      high-level disinfection;

      storage under conditions precluding secondary contamination by microorganisms.

      The sequence of treatment stages of endoscopic equipment and endoscopes for sterile endoscopic interventions, all kinds of their instruments for sterile and non-sterile interventions immediately after their use is as follows:

      pre-cleaning;

      pre-sterilization cleaning combined with disinfection;

      sterilization;

      storage under conditions precluding secondary contamination by microorganisms.

      After each use of the endoscope, all stages of its treatment shall be carried out in full. All channels of the endoscope shall be treated, regardless of whether or not they were involved in an endoscopic intervention.

      The endoscope can transmit a pathogen in case of violation of its leakproofness, manufacturing defects, inappropriate cleaning and (or) inefficient high-level disinfection, insufficient drying of its channels. Residual organic contamination (in case of poor-quality cleaning) and storage in the wet state contribute to the reproduction and accumulation of microorganisms in endoscopes with the formation of biofilms. Inside a biofilm, microorganisms are protected from the action of disinfectants.

      All patients are considered as potential sources of infectious agents, and therefore all endoscopes and their accessories, after their use, shall be treated according to a single standard.

      Each endoscope is given an individual code that contains information on its model and serial number. The code is indicated in the special note column of the register of examinations carried out in the department, unit, office of endoscopy, in the protocol of endoscopic examination.

      A medical worker treating endoscopes and their instruments shall put on personal protective equipment including: disposable gloves made of a chemically resistant material, goggles, a mask or a face shield; a gown or a cloak (long-sleeved, waterproof one) or a disposable waterproof apron with sleeves (sleevelets).

      To prevent the formation and spraying of microbial aerosols in the course of treatment of endoscopes and channel instruments, manual cleaning manipulations are carried out with full immersion of products in a solution, also in case of using washing guns, the fluid pressure in which is set to the lowest sufficient level. Endoscopic channels for non-sterile interventions after final cleaning are dried using the method of air aspiration or air purging after the channels are closed with wipes.

      To reduce the risk of infection of the personnel and ensure reliable treatment of flexible endoscopes for non-sterile interventions, a mechanized method using washing and disinfecting machines is used. With a large turnover of endoscopes (in case of simultaneous treatment of three or more endoscopes of the same type), the mechanized method of treating endoscopes is mandatory.

      To prevent injuries from endoscope instruments with piercing-cutting surfaces, the personnel’s contact with untreated instruments shall be minimized using containers with perforated tabs, washing and disinfecting machines and ultrasonic cleaners.

      It is not allowed to use injection needles to collect pathological material from branch biopsy forceps. браншейбиопсийных

      For non-sterile endoscopic interventions, it is necessary to use endoscopes, which are reusable products, disposable and/or reusable instruments, additional endoscopic equipment (illuminator, insufflator, endovideo system, monitor, irrigator-aspirator and others).

      The sequence of treatment processes of endoscopes for non-sterile endoscopic interventions after each use is as follows: pre-cleaning (PC), independent final cleaning (hereinafter referred to as FC) or FC combined with disinfection (hereinafter referred to as FC+ D), high-level disinfection (hereinafter referred to as HLD).

      The pre-cleaning of external surfaces of an endoscope means their wiping with disposable wipes or sponges moistened with a detergent solution. The channels are rinsed with a detergent solution and/or water.

      Final cleaning is the most important stage of the treatment of an endoscope, which is essential for the efficiency of HLD following it. It is carried out as an independent process or in combination with disinfection, which depends on the means used for these purposes (detergents or detergents-disinfectants).

      Detergents based on enzymes and/or surface-active materials (hereinafter referred to as SAM) do not contain antimicrobial components, therefore their solutions are used for the final cleaning of endoscopes only once.

      Disinfectants with low foam formation, without fixing properties in the concentrations used, shall be used for the cleaning combined with disinfection before first visual signs of contamination appear, but only during one work shift, and to prevent cross-contamination, endoscopes examining the upper, lower gastrointestinal tract (hereinafter referred to as GIT) and those for examining the respiratory tract shall be treated separately.

      After draining a washing (washing-disinfecting) solution, a washing bathtub shall be cleaned and disinfected by wiping with a disinfectant applying the mode effective against viruses, mycobacteria and Candida species and used again for treating an endoscope of any model (gastroscope, colonoscope, bronchoscope and others).

      High-level disinfection is performed manually (with full immersion in a solution) or mechanically. High-level disinfection of endoscopes by wiping is not allowed.

      The permissible level of disinfection of rigid and flexible bronchoscopes at the final stage of treatment is high-level disinfection, however, if a health facility has required medical conditions and equipment, they can be sterilized. Rigid endoscopes for examining the gastrointestinal tract (rectoscopes), ENT organs (rhinoscopes, laryngoscopes, otoscopes, and others) are also subjected to HLD or sterilization (usually with saturated steam under pressure in accordance with manufacturers’ recommendations) at the final stage of their treatment.

      Endoscope instruments, regardless of the type of endoscopic intervention (sterile, non-sterile) shall be kept sterile. After use, the sequence of their treatment is as follows: pre-cleaning, pre-sterilization cleaning combined with disinfection, sterilization.

      Pre-cleaning is carried out in the endoscopic manipulation room by fully immersing instruments in a solution of detergent (detergent-disinfectant) agent without fixing properties. After the stage of soaking is over, the solution is drained, the instruments are rinsed with water on a perforated tray (if there is a washing tank for instruments in the endoscopic manipulation room). If there no conditions for draining the solution and rinsing the instruments, it is allowed to take them to the washing-disinfection room or the central sterilization department (hereinafter referred to as CSD) in the solution in a closed container.

      Pre-sterilization cleaning combined with disinfection is carried out in a solution of a disinfectant without fixing properties in the concentration applied.

      It is allowed to postpone the sterilization of endoscope instruments until the beginning of the next shift, provided that the products have been disinfected, pre-sterilized, and well dried.

      The means, method and mode of sterilization are chosen with account of recommendations of the instrument manufacturer. It is preferable to sterilize endoscope instruments mechanically; sterilization with chemical solutions is allowed if other methods are not available.

 **1. The standard of treatment of an endoscope for non-sterile interventions**

|  |  |
| --- | --- |
|
Location |
Sequence of treatment of an endoscope manually and mechanically (in a washing-disinfecting machine (hereinafter referred to as WDM)  |
|
Endoscopic manipulation  |
Pre-cleaning
Wiping of the surface, flushing of channels, external assessment of leakproofness  |
|
Washing-disinfection room |
Leakproofness test  |
|
Final cleaning or final cleaning combined with manual disinfection using brushes for accessible channels, valves, valve sockets, elevator and the area around it (if any) |
|
Full cycle of treatment in WDM  |
HLD in WDM |
Manual HLD  |
|
FC by rinsing with detergent solutions
Rinsing
HLD
Rinsing
Drying
Washing with 70% ethyl or isopropyl alcohol
Air purging |
HLD
Rinsing
Drying
Washing with 70% ethyl or isopropyl alcohol
Air purging |
HLD
Rinsing
Drying
Washing with 70% ethyl or isopropyl alcohol
Air purging |

 **2. The content and conditions for efficient treatment of endoscopes for non-sterile**
**interventions manually**

|  |  |  |
| --- | --- | --- |
|
Sequence and content of stages for PC, FC/FC+D, HLD |
Material and technical support of treatment |
Conditions for efficient implementation of a particular stage or process of treatment |
|
1 |
2 |
3 |
|
1. Pre-cleaning. Carried out in the endoscopic manipulation room before the endoscope is disconnected from the light source and the aspiration pump. Designed to remove massive, including visible, contamination from the surface and out of the endoscope channels to prevent them from drying out |
|
Within 10 sec., to carry out air aspiration through the biopsy-aspiration channel system (hereinafter referred to as BA) to prevent the flowing of biological fluids from the biopsy channel  |
Personal protective equipment (hereinafter referred to as PPE) of the personnel.
Equipment (light source and aspiration pump).
Flushing tubes of additional channels, if any.
Waterproof cap for a video endoscope of some manufacturers.
An adapter for cleaning the air/water feed channel of some manufacturers.
Disposable or treatable containers with a capacity of at least 200 ml for a washing solution and water.
Prepared detergent solution.
Clean wipes or disposable sponges.
A class B container for disinfection or for collecting medical waste |  |
|
To wipe the working part of the endoscope starting from the control unit towards the distal end with a clean disposable cloth (sponge) moistened in a detergent solution, the flexible part - with rotational movements |
Dispose of the used wipe in a disinfecting solution or a class B waste container. The sponge is used to perform FC/FC + D, and then put in a disinfecting solution or a class B waste container  |
|
To wash the BA channel system with a cleaning solution. To put the distal end of the endoscope into a container with 150-200 ml of detergent solution. By turns, to aspirate the solution and air. To complete the procedure with air aspiration  |
Do not overfill the aspiration jar  |
|
To wash the BA channel system with water, putting the distal end into a container with water for 10 sec., to complete the procedure with air aspiration  |
The stage is performed if, during pre-cleaning and final cleaning, various means are used to prevent problems with their compatibility |
|
To wash the channels and air and water nozzles with water in accordance with the manufacturer’s instructions |  |
Pre-replace the air-water valve (hereinafter referred to as AW) with an adapter for cleaning the AW supply channel (if this is prescribed by the manufacturer’s instructions) |
|
To wash additional channels (if any) with water or a detergent in accordance with the manufacturer’s instructions |  |
All channels are subject to treatment, even if they were not used in a previous examination |
|
To disconnect the endoscope from the illuminator, video processor, aspiration pump, to remove the valves  |  |
|
To attach a waterproof cap (plug) to the endoscope’s connector  |
The procedure is performed while treating the video endoscope |
|
To take the endoscope to the washing room  |
To transport along the corridors of a department (health facility) in a closed form on a tray  |
|
Leakproofness test1) Allows to confirm the watertightness (leakproofness) of the endoscope before it is immersed in a solution of a chemical agent to avoid serious damage when being in contact with it  |
|
The use of a leak detector2): |  |  |
|
To connect the leak detector to the air supply unit |
Personal protective equipment.
Air supply unit.
Leak detector (of various types).
Washing tank.
Drinking running water. |
To get sure the air flows through the leak detector |
|
To attach the leak detector to the endoscope and to supply air to create excess pressure in the device.
When using a handheld leak detector, overpressure is created using a rubber bulb to the level indicated on the pressure gauge (“dry test”). To observe the pressure gauge for the time specified by the manufacturer of the endoscope.  |
Whether the air flows into the endoscope, it is necessary to check the stretching of the outer coating.
The level of pressure created within the values recommended by the manufacturer of the endoscope |
|
When using a tester with the automated detection of air leakage, follow the tester manufacturer’s instructions  |  |  |
|
To fully immerse the endoscope in water. Using the screws of the control unit, to change the bending angle of the inserted tube in all directions. To observe the surface of the immersed endoscope for the time specified by the manufacturer (test for leaks in water). It is carried out independently or as the second stage after the completion of the “dry test”  |
Leaks in the endoscope are identified when single air bubbles or a track of them appear.
If a leak is detected, it is necessary to follow the manufacturer’s requirements without disconnecting the tester  |
|
To remove the endoscope with a leak detector from water, to turn off the air supply to the tester (to relieve pressure when using a manual leak detector), in a few seconds, to disconnect the tester from the air supply unit and then from the endoscope  |  |
|
2. Final cleaning or final cleaning combined with disinfection is carried out in order to remove as much as possible contamination of all types, including drugs and microorganisms, from the surface and out of the endoscope channels  |
|
1stage. FC/FC + D of the surface and channels of the endoscope |
|
To fully immerse the endoscope and its removable parts into the solution of a detergent or a disinfectant-detergent, filling all channels through accessories with a syringe or a pump. To detach accessories leaving them in the solution |
Washing tank with a capacity of at least 10 liters with a lid. The working solution of a detergent or a disinfectant-detergent prepared in accordance with the instructions for use in the FC or FC + D mode.  |
Complete filling of the channels is indicated by that air bubbles stop coming out of outlet openings of the endoscope |
|
To keep in the solution for the time specified in the instructions for use of the agent used |
Running drinking water.
Clean disposable lint-free wipes/sponges.
Accessories for treating the channels of the endoscope3).
A syringe with a capacity of 20-30 cm3 (20-30 ml) or a pump.
Timer.
Thermometer.
Sterile reusable or disposable brushes4).
A container with a disinfectant solution without properties fixing biological contamination for pre-sterilization cleaning combined with disinfection (hereinafter referred to as PSC + D) of reusable brushes.
Container for disinfection or for collecting class B medical waste  |
To strictly observe the mode of application of the product: the concentration of the solution, the exposure time, the temperature of the solution  |
|
After holding in the solution, to clean the outer surface of the endoscope from contamination with clean disposable wipes or sponge |
To dispose of used wipes in a container with a disinfectant or a container for collecting class B medical waste |
|
Using special brushes, to clean the valve and the air/water supply adapter, the aspiration valve, the biopsy valve, the end part of the insertion tube, the elevator mechanism (for the duodenoscope), the valve seats, as well as all accessible channels in accordance with the manufacturer’s recommendations. To continue treating the channels until no visible dirt is detected on the brush (at least 3 times) |
All cleaning procedures shall be carried out with full immersion of the endoscope and removable accessories into the solution in order to avoid the splashing of contaminated liquid.
Serviceable brushes with the diameter of a channel under treatment.
Every time a brush goes out of the channel, it is cleaned in a solution removing visible dirt. |
|
To attach accessories for the treatment of the channels, through which all the channels are rinsed with a solution of an agent with a syringe/pump to remove any residual contamination. To strictly follow the manufacturer’s instructions |
To carry out these procedures with full immersion of the endoscope in a solution  |
|
To remove the solution from the channels with the air using accessories  |
To carry out these procedures with full immersion of the endoscope in a solution  |
|
2 stage. Rinsing the endoscope from residues of a detergent/a disinfectant-detergent
It is carried out in order to remove residues of an agent used for FC or FC + D from the surface and channels of the endoscope  |
|
To immerse the endoscope in running drinking water. Using the shower head, to thoroughly rinse the external surfaces of the endoscope and its accessories  |
Washing tank with a capacity of at least 10 liters (when using solutions of detergents for single use, all the stages of final cleaning in one tank are allowed).
Running drinking water.
Accessories for treating the channels of an endoscope.
Syringe with a capacity of 20-30 cm3 (20-30 ml) or pump |
For rinsing each endoscope, to use a new portion of running drinking water |
|
To rinse the channels through accessories with a syringe or a pump |
To rinse each channel with at least 90 ml of water with a syringe, or to pump water with a pump for at least 1 min. |
|
3 stage. Drying the endoscope after rinsing
It is conducted to prevent an agent for HLD from diluting with water  |
|
To dry the outer surface of the endoscope with clean wipes. To remove water from the channels by air purging or aspiration through accessories with a syringe or a pump  |
Table/worktop or washing tank, in which rinsing was held.
Clean sheet (diaper).
Clean wipes.
Accessories.
Syringe/pump  |
The channel outlets during purging shall be covered with wipes to prevent the formation of microbial aerosols. To dispose of the used wipes in a container for disinfection or in a class B waste container |
|
Evaluation of the quality of cleaning using:
- azopyramic or another test regulated for this purpose5);
- phenolphthalein test6) |
After using chemical solutions (azopiram, phenolphthalein), to rinse the biopsy channel with 20–30 ml of running drinking water and purge it with air, and wipe the outer surface first with a cloth moistened with running water and then with a dry cloth  |
|
3. High-level disinfection
It is performed in the HLD area of the washing-disinfection room.
It is carried out in order to destroy vegetative forms of bacteria (including mycobacteria), fungi, viruses and reduce the number of spore forms of microorganisms on/in the endoscope |
|
1stage. Exposure to disinfection  |
|
To fully immerse the endoscope in a disinfectant solution, to fill the channels through accessories with a syringe or a pump |
Disinfected container with a capacity of at least 10 liters with a lid.
The working solution of the HLD agent of multiple use from groups of chemicals in sterilizing (sporicidal) concentration.
Accessories for treating channels.
Syringe or pump7).
Timer.
Water thermometer.
Chemical indicators8) |
Complete filling of the channels is indicated by that air bubbles stop coming out of outlet openings of the endoscope  |
|
To disconnect the accessories, to fill them with a solution of HLD agent using a syringe and leave them in the solution together with the endoscope, to remove the syringe and throw in a class B waste container.
To remove air bubbles from the external surfaces of the endoscope and accessories with a wipe |
Full contact of all elements of the endoscope and accessories with the solution of the HLD agent is ensured |
|
Exposure to disinfection in a solution. When using the pump, the solution forcibly circulates through the channels during the time of disinfection exposure |
To monitor the mode of application of a solution or a HLD agent ready for use: the concentration of a disinfecting substance (hereinafter referred to as DS) by chemical indicators (at least once a shift), temperature by a thermometer, disinfection exposure by a timer |
|
After disinfection exposure is over, to blow the solution out of the channels with air manually using newly attached accessories and a sterile syringe or using a pump |
Accessories.
Sterile syringe or pump.
Alcohol-based skin antiseptic.
Sterile gloves |
The stage is carried out in compliance with the rules of asepsis. The personnel take off a dressing gown or apron, sleevelets, gloves in the cleaning zone, enter the HLD zone, hygienically clean hands and put on sterile gloves before manipulations with the disinfected endoscope |
|
2 stage. Post-HLD rinsing |
|
To put the endoscope with attached accessories in a washing tank/container with water of a regulated microbiological quality. To rinse the channels of the endoscope through accessories with a sterile syringe/pump, to displace water with air. To detach accessories from the endoscope. To rinse the outer surfaces of the endoscope using sterile wipes and/or a shower head. To thoroughly rinse the accessories with water  |
A washing tank with a volume of at least 10 liters for rinsing gastrointestinal endoscopes or a container of sufficient volume for rinsing bronchoscopes with their full immersion.
Running drinking water for rinsing gastrointestinal endoscopes.
Sterile water, boiled water or water purified through antimicrobial (arresting particulates larger than 0.2 microns) filters for rinsing bronchoscopes.
Accessories.
Sterile syringe or pump |
The stage is performed in compliance with the rules of asepsis. The rinsing procedure is prescribed in the instructions for the agent used (frequency and duration of rinsing). The volume of water used to rinse each channel cannot be less than 90 ml.
Water for rinsing ma be used only once |
|
3 stage. Drying of the endoscope |
|
To take the endoscope and accessories out of water and put them on a sterile sheet (before, water out of them shall be drained). Using sterile wipes, to dry the outer surfaces of the endoscope, valves. To attach accessories and dry the channels by air purging or aspiration through a sterile silicone tube |
Sterile wipes.
Sterile sheet.
Accessories.
Sterile silicone tube and vacuum aspirator or sterile syringe or pump |
The stage is performed in compliance with the rules of asepsis. |
|
To wash the endoscope channels and the elevator area (for a duodenoscope) with alcohol and purge them with air |
70% ethyl or isopropyl alcohol.
Accessories.
Sterile syringe |
The amount of alcohol used corresponds to the volume of flushed channels of a specific model of an endoscope  |
|
1) The method of testing for leakproofness, the equipment and procedure for testing are determined by the endoscope’s manufacturer.
2) A method for disinfecting a leak detector is specified in the instructions for its use.
3) Accessories for treating channels of the endoscope (devices for washing and filling channels with a detergent solution, water, solution of an agent for HLD, alcohol and air: irrigator of the aspiration channel and AW channels, adapter for aspiration of the biopsy channel, flushing tubes of additional channels) together with the endoscope are subject to the full treatment cycle in case of manual operation, after which they can be immediately reused.
4) After its use, a reusable brush is subjected to PSC + D and sterilized as endoscope instruments. When using single-use brushes, it is necessary to follow the manufacturer’s instructions for compliance with the channel diameters and the cleaning procedure.
5) Every tenth treated endoscope is tested for the quality of cleaning, but at least one per shift.
6) Phenolphthalein test is used when using solutions for cleaning with pH 8.5 and above.
7) During a HLD process (disinfection holding, rinsing, drying), it is necessary to use a pump installed in the HLD zone.
8) Chemical indicators to assess the concentration of DS in the working solution of a disinfectant are used in accordance with the instructions of the manufacturer of disinfectants and chemical indicators  |

 **3. Requirements for the mechanical treatment of endoscopes for non-sterile interventions.**

      The use of a WDM is a main measure to reduce the risk of infection of patients with endoscopic interventions due to standardized and validated treatment processes carried out in a closed cycle, the ability to control and document the critical parameters of HLD, ensuring the rinsing and drying of the channels of the endoscope after HLD with water and air purified through antimicrobial filters in the automatic mode.

      Before each treatment cycle in a WDM, the endoscope is subjected to manual final cleaning using brushes, unless otherwise indicated in the instructions for the machine’s use.

      Before putting into operation for the first time, after repair or long-term (over 1 month) downtime, the final cleaning process in a WDM is validated using tests allowed for these purposes in the Republic of Kazakhstan.

      Accessories that were used before the automatic cycle in a WDM for manual final cleaning are subject to disinfection in a disinfectant solution using the mode effective against viruses, bacteria and fungi of the Candida genus (in health facilities treating the tuberculosis - according to the tuberculocidal mode of the disinfectant tested for Mycobacterium terrae).

      Endoscopes for examining the respiratory tract may be treated in one WDM provided the below indicated conditions are observed:

      HLD agents are recommended by manufacturers in the WDM instruction manual (the efficiency of the automated cycle has been proven for them);

      the above HLD agents are applied once or multiply. In this case, WDMs using HLD agents multiply are provided with the means of chemical control of the concentration of a DS in the finished product/working solution (chemical indicators) and the function of indicating the maximum number of treatment cycles/days of use of the solution;

      a WDM has original adapters for connecting all channels of endoscopes under treatment.

      For the treatment of bronchoscopes, a separate WDM is allocated if it is impossible to fulfill even one of the above conditions.

      It is forbidden to jointly treat bronchoscopes and gastrointestinal endoscopes in one cycle.

      It is not allowed to use a WDM for treating bronchoscopes without antimicrobial filters for water purification, which arrest microorganisms larger than 0.2 microns in size.

      If there is no option for additional drying with 70% ethyl or isopropyl alcohol in a WDM, this stage is carried out manually after taking the endoscope out of the machine.

      Self-disinfection of a WDM is carried out within terms, using the agent and by the mode specified in the instruction manual of the machine. In case of no such indications, the self-disinfection is carried out when changing the solution of an HLD agent. It is not allowed to use apply the spent solution to the HLD of endoscopes for this purpose.

 **4. Requirements for transportation and storage of endoscopes for non-sterile interventions**

      Endoscopes are transported closed, on trays or in containers between the rooms of the endoscopic department, to the CSD, other departments of a health facility, as well as when providing medical care outside a health facility. For packaging, labeled polyethylene (sterile and non-sterile) inserts, woven and non-woven material (sterile, for packaging treated endoscopes) are used.

      To prevent the mixing of clean and dirty endoscopes during transportation, various marking options are provided: labeling of trays, colored polyethylene inserts or disposable tags, and others.

      After their use, trays are treated by wiping with a disinfectant according to a mode effective against viruses, bacteria and fungi of the Candida genus (in health facilities treating the tuberculosis - according to the tuberculocidal mode of the disinfectant tested for Mycobacterium terrae).

      In between shifts, treated endoscopes are stored unassembled, packaged in sterile material or unpacked under aseptic conditions in specialized (for storage (storage and drying) cabinets with a registration certificate. The shelf life of endoscopes in a cabinet for drying and storage in an aseptic environment is indicated in the instruction on the operation of the cabinet. The shelf life of endoscopes packed in sterile textile covers does not exceed 72 hours. After expiration of the storage period, the endoscope is subject to HLD again.

      In specialized cabinets for storage/storage and drying of endoscopes, there shall be the recirculation of the air, which is decontaminated by ultraviolet radiation and/or antimicrobial filters. Removable parts are stored separately from the endoscope in the cabinet, but it is necessary to mark them as parts belonging to a specific product.

      After the treatment cycle is over, the endoscope, before being used again, is stored assembled in a sterile package on a tray for no more than 3 hours. If the endoscope is not used within the specified time, it is subject to new HLD and drying.

 **5. Requirements for treating endoscope instruments**

      Endoscope instruments are characterized by a complex structure, they also have piercing-cutting surfaces, and therefore pose a risk of injury to medical personnel at the treatment stages.

      Endoscope instruments, regardless of the type of endoscopic intervention (sterile, non-sterile) shall be kept sterile. After their use, they are sequentially subjected to pre-cleaning, pre-sterilization cleaning combined with disinfection, sterilization.

      Simultaneous treatment of instruments in the same container/washing tank is not allowed.

      Most instruments, including those with channels, are disposable products and cannot be re-treated.

 **6. The content and conditions for efficient manual treatment of endoscope instruments:**

|  |  |  |
| --- | --- | --- |
|
Sequence and content of stages of PC, PSC + D, sterilization |
Material and technical support of treatment |
Conditions for efficient implementation of individual stages and/or entire process of treatment |
|
1 |
2 |
3 |
|
1. Pre-cleaning
Conducted in the endoscopic manipulation room. Designed to remove massive dirt (before its drying) from/out of an instrument  |
|
Removal of massive dirt from an instrument by a wipe (swab) |
PPE of the personnel.
Disposable clean wipes (swabs), dry or moistened with a detergent.
Container with perforated tray of sufficient capacity for full immersion of instruments.
Target detergent (preferably enzymatic) agent.
Syringe or another device for flushing channels  |  |
|
Full immersion in a container with a detergent solution. Channels and cavities, if any, are filled forcibly. |
The minimum time of holding in a solution is indicated in instructions for the agent’s use, the maximum time is in accordance with the manufacturer’s recommendations |
|
Rinsing of instruments by spraying water on a perforated tray (given a washing tank for instruments).
Transportation to the CSD or washing-disinfection room  |
Instruments are transported wet (after rinsing) or in a solution
(without rinsing) |
|
2. Pre-sterilization cleaning combined with disinfection\*
Carried out in the washing-disinfection room or CSD for disinfection and best possible cleaning |
|
Full immersion in a solution. Channels and internal cavities (if any) in reusable instruments are filled forcibly.
Disinfection exposure  |
Containers with perforated trays.
Ruffs, brushes, a washing gun with nozzles, wipes.
Disinfectant with detergent properties in the “PSC + D” mode of application for endoscope instruments. |
To observe the mode of application of the working solution of a disinfectant: concentration (when preparing the solution, a measuring container shall be used), temperature (to monitor with a thermometer), time of disinfection exposure (to monitor with a timer) |
|
Cleaning in the same solution using wipes, brushes and ruffs |
Running drinking water.
Distilled water |  |
|
Rinsing with running water, including internal cavities and channels forcibly.
Rinsing with distilled water |  |
Water for rinsing is used only once |
|
Drying with clean wipes, air gun  |
Clean material.
Air gun.
Bracket or another device for drying long instruments |
Before packing, long products are dried flat on brackets |
|
Tests for the quality of cleaning (azopiramic, phenolphthalein or other tests regulated for this purpose) |
|
Functional tests. Greasing. Conducted to monitor and support the instruments’ functions  |
|
Packing before loading into a sterilizer  |
Packaging materials corresponding to the selected sterilization method  |
To ensure the safety of the instrument, sterilization containers recommended by manufacturers shall be used  |
|
3. Sterilization
Held in the sterilization room of the endoscopic department, CSD  |
|
Manually, in a solution of chemical agents:
- full immersion in the solution of sterilizing agent;
- rinsing with sterile water;
- drying with sterile material |
Sterile containers.
Sterilizing agent from groups of oxygenative or aldehyde containing chemicals.
Chemical indicators.
Timer.
Thermometer.
Sterile water for rinsing.
Sterile material |
Sterilization parameters are assessed (solution concentration and temperature, time of sterilization exposure).
All operations with the instrument after its removal from a sterilizing agent are carried out under aseptic conditions.
A sterile container and sterile water for rinsing are used only once |
|
In steam, gas sterilizers (using ethylene oxide, formaldehyde), as well as in sterilizers using hydrogen peroxide vapor (including plasma) |
Sterilizer  |
The mode of sterilization from among the sterilizer operation programs is chosen with account of recommendations of the manufacturer of a particular medical device |
|
When using products not having both detergent and disinfectant properties, the pre-sterilization cleaning and disinfection processes are carried out independently (without being combined). |
|  |  |  |

      Pre-sterilization cleaning as an independent process and when combined with disinfection is carried out mechanically in ultrasonic installations (hereinafter referred to as USI) using the agents, for which the corresponding mode of application was developed and specified in the instructions.

      The processes of mechanical cleaning and disinfection of instruments are fully performed in specialized WDMs. The choice of cleaning and disinfecting agents is determined based on the recommendations of the manufacturers of instruments and a WDM.

 **7. Algorithm for treating ultrasound through esophageal sensors**

|  |  |  |
| --- | --- | --- |
|
Process/stages |
Manually  |
Mechanically  |
|
PC |
To clean the insertion portion of the sensor with a cloth moistened with a detergent. To disconnect the sensor from the system and remove all accessories connected or attached to the sensor. To wipe the sensor with a dry cloth |
|
FC/FC+D |
To immerse the sensor to the mark fixed by the manufacturer in a detergent/disinfectant solution for the time specified in the instructions for the agent’s use. To use a cloth for cleaning. To rinse in drinking water. To dry with a clean cloth |
To use a WDM. To immerse the sensor to the manufacturer’s mark. To perform a full cycle including FC and HLD  |
|
HLD |
To immerse the sensor to the mark fixed by the manufacturer in the solution of a HLD agent for the period of disinfection exposure. To rinse in drinking water, to dry with sterile material |
|
Storage  |
In aseptic environment  |
|
The sensor’s parts that are not immersed shall remain dry, for that reason they are held above the parts that are immersed in the solution of a chemical agent and rinsed in water. |

      8. The management of measures to prevent infections associated with non-sterile endoscopic interventions

      Endoscopes are treated by trained medical personnel specially assigned thereto.

      A health facility creates a system of continuous training for medical personnel involved in the treatment of endoscopes (primary on-the-job training when beginning to work, training in the treatment of new endoscope models, training in mechanized procedures for the treatment of an endoscope when a new WDM is put into operation, once every 5 years – qualification improvement in accordance with programs).

      A health facility conducting non-sterile endoscopic interventions is equipped with the necessary number of endoscopes and their instruments, equipment for cleaning and storing endoscopes, means of cleaning, disinfecting, HLD and other consumables.

      The number of endoscopes in a particular health facility is determined on the basis of the workload, the total time of the endoscopic intervention and the full cycle of the endoscope treatment. The approximate number of endoscopes of each model (gastroscopes, colonoscopes, bronchoscopes, duodenoscopes, and others) for performing the planned number of interventions is calculated using the formula:

      h = n × (a + b) : c, where

      a – is the average duration of the full cycle of the treatment of an endoscope of a particular model, min;

      b – is the average duration of the intervention performed by the endoscopes of this model, min;

      c – is the duration of a work shift, during which endoscopic interventions are performed by this model of endoscopes, min;

      n – is the planned or actually performed number of interventions by this endoscope model.

      h – is the resulting value.

      The values *a* and *b* are determined by timing the duration of several endoscope treatment cycles for each endoscope model or endoscopic interventions carried out using them, respectively. The resulting value *h* is rounded up to the nearest integer.

      With a large load (three or more endoscopes of the same type are treated simultaneously), the use of a WDM is mandatory.

 **9. Procedure for conducting routine microbiological quality control of the treatment**
**of endoscopes for non-sterile interventions and their instruments**

      The quality of treating endoscopes is assessed using the microbiological method.

      Scheduled sampling of washings is carried out from/out of a completely treated and dried endoscope quarterly. Samples are taken by a laboratory technician or microbiologist with the help of a nurse from the department. Subject to control are: biopsy channel, insertion tube, valves and valve sockets.

      Washings from the outer surface of the insertion tube of the endoscope are taken with sterile swabs moistened in sterile distilled water according to the standard procedure.

      Washings from all surfaces of each valve (outer surfaces, surfaces of hollow spaces and through holes) are taken with one swab. Washings from the surfaces of the valve seat are taken in a circular movement of the swab from the entire surface of the cylinder.

      The criterion for the efficiency of complete cycle of treatment of an endoscope is the lack of growth of bacteria of the group of Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, mold and yeast fungi, as well as other opportunistic and pathogenic microorganisms. Under this condition, the indicator of total microbial contamination of the endoscope biopsy channel is less than 100 CFU/ml.

      If microorganisms are detected or the biopsy channel is contaminated with microorganisms in the amount of 100 CFU/ml, the treatment is considered unsatisfactory. The endoscope shall undergo a complete treatment cycle and control sampling. With repeated unsatisfactory results of microbiological examination and in case of no identified violations in the technology of treatment of the endoscope, it is recommended to contact the service center to test its technical health.

      Unscheduled microbiological assessment of the quality of treatment of the endoscope is carried out given epidemic indications.

      Microbiological assessment of the quality of self-disinfection of a WDM is carried out at least once every six months. Washings from different parts of the machine (bathtub, water and air supply pipes, fittings) are taken with swabs moistened with sterile distilled water immediately after the completion of self-disinfection cycle. The criterion of efficiency is the absence of growth of vegetative forms of microorganisms in the samples of washings.

      Endoscope instruments subject to sterility testing are sent to the microbiology laboratory in the package, in which they were sterilized. The criterion for sterilization efficiency is the absence of growth of microorganisms.

 **10. Requirements for conducting preventive disinfection in the endoscopic department/room**

      Manipulation rooms for non-sterile endoscopic interventions and the washing-disinfection room are cleaned and disinfected if they are contaminated, but at least once a shift or 2 times a day. For this purpose, a general hospital uses a disinfectant according to the mode ensuring the death of viruses, bacteria and fungi of the Candida genus; in health facilities treating tuberculosis - according to the mode ensuring the death of mycobacteria; in other infectious hospitals - according to the mode ensuring the death of the most resistant pathogen (viruses, mycobacteria of tuberculosis or other microorganisms according to the type of the hospital).

      After each patient, in the endoscopic room, the surface of a couch (table) for examination and additional endoscopic equipment with which he/she was in contact, are subjected to disinfection using the agents with short disinfection exposure. For each patient, a couch/table is covered with a clean sheet.

      Washing tanks are disinfected using the wiping method, and accessories for treating the endoscope channels are disinfected by the immersion method after the completion of the final cleaning process (without combining with disinfection) of each endoscope.

      At the end of a work shift, in the washing-disinfection room, it is mandatory to disinfect:

      all containers and washing tanks for final and pre-sterilization cleaning, rinsing endoscopes after HLD, sinks for washing hands by medical personnel, all horizontal surfaces;

      an aspiration jar and connecting tubes. An aspiration jar is disinfected when it is fully immersed in the solution of an agent without biological contaminant-fixing properties, then it is cleaned with the help of ruffs and brushes. Tubes are recommended to be cleaned and disinfected in a WDM in the CSD. In case of no WDM, tubes are treated manually in a solution of active oxygen agents using devices for pumping solutions (for example, a pump, a syringe, and others). The treatment is completed by checking the tubes for integrity and drying with clean material, a pump or an air gun;

      a tank (container, jar) for water intended for cleaning lenses, a cover and its connecting tubes shall be cleaned, dried and sterilized at the end of a work shift. The cover and connecting tubes are cleaned using ruffs and brushes, after which they are thoroughly dried, packaged and sterilized. Before beginning endoscopic examinations, a sterile jar is filled with sterile water;

      the air-water circuit of a pump used in the final cleaning process is disinfected by continuously pumping a disinfectant solution applied according to the mode ensuring the death of viruses, bacteria and fungi of the Candida genus (in health facilities treating tuberculosis - according to the mode ensuring the death of mycobacteria), then it is washed with water during the time specified in the instructions for the applied agent, and purged with air.

 **11. Development and implementation of a program for internal quality control of treating**
**endoscopes in the endoscopic department (room)**

      A program for internal quality control of treating endoscopes is developed in the endoscopic department (room). The program includes:

      periodic (monthly) visual inspections of FC (FC+D) process by the person responsible for organizing and conducting infection control, including the quality of treating endoscopic equipment;

      senior nurse’s weekly testing of the quality of endoscopes’ cleaning using tests regulated for this purpose and the concentration of the active substance in the reusable HLD working solution using chemical indicators;

      microbiological assessment of the quality of the endoscope’s full cycle of treatment (quarterly) and the quality of self-disinfection of a WDM (2 times a year).

      development and implementation of the schedule of preventive maintenance of endoscopes;

      scheduling the maintenance of a WDM (replacement of water and air filters, validation of the quality of cleaning endoscopes);

      assessment of the observance by the personnel of the endoscopic department (room) of the hand hygiene rules, use of non-sterile (sterile) gloves, and other PPE;

      checking of the personnel’s knowledge of techniques for preventing the formation of microbial aerosols during the cleaning of endoscopes, procedures for safe handling of piercing-cutting instruments, medical waste;

      checking of the personnel’s readiness for emergency response (spilling of chemicals or biological fluids, ingress of biological fluids on the body, injuries with non-sterile instruments).

 **12. Treatment of flexible endoscopes for sterile endoscopic interventions**

      Flexible endoscopes for sterile endoscopic interventions after their use are treated in the following sequence: pre-cleaning, pre-sterilization cleaning combined with disinfection, sterilization; storage under conditions precluding secondary contamination by microorganisms.

      Pre-cleaning, pre-sterilization cleaning, the cleaning process combined with disinfection of flexible endoscopes are carried out in accordance with the requirements set for endoscopes for non-sterile interventions.

      Flexible endoscopes are sterilized in solutions of chemical agents manually or mechanically in low-temperature sterilizers without restrictions on the use for a specific endoscope model (by materials, number, length and diameter of the channels).

      The process of manual sterilization of endoscopes includes the following steps:

      Exposure to sterilization in the solution of one of disinfectants, with full immersion of the endoscope and forced filling of the channels through adapters (flushing tubes), as well as removing air bubbles from the outer surfaces;

      The endoscope is rinsed with sterile water in accordance with instructions for the use of a specific sterilizing agent. Internal channels are rinsed through adapters, flushing tubes.

      Sterile water and sterile water containers are used only once.

      The outer surfaces of an endoscope are dried with sterile wipes, the channels - with air under pressure or by air aspiration. Additional drying of channels with alcohol is not carried out. Products, washed from the remnants of sterilizing agents and dried, are put into a sterile sterilization box, lined with a sterile cloth. The permissible shelf life of sterilized products is not more than 72 hours.

 **13. Treatment of rigid endoscopes for sterile surgical interventions**

      The treatment of rigid endoscopes for sterile surgical interventions includes the following processes: pre-cleaning, pre-sterilization cleaning combined with disinfection, sterilization.

      Pre-sterilization cleaning, combined with disinfection, of rigid endoscopes and their accessories is carried out manually or mechanically in a WDM.

      The process of pre-sterilization cleaning combined with disinfection, in case of manual treatment of an endoscope, includes the following steps:

      disinfection exposure in a washing-disinfecting solution with full immersion of the endoscope in the solution and forced filling of its channels;

      mechanical cleaning of internal channels and removable parts of the endoscope with the help of brushes and wire cleaners of an appropriate size;

      washing the internal channels with the help of special tools (syringe pipes, washing syringes or a washing gun with nozzles);

      rinsing the endoscope with drinking water and distilled water, including channels using special tools.

      The outer surfaces of the endoscope are dried with a soft cloth, the channels - with air using air guns. Additionally, optical surfaces are dried with 70% alcohol, if indicated in the manufacturer’s instructions.

      Mechanical pre-sterilization cleaning combined with disinfection is carried out in a WDM using chemical agents or chemical agents and the thermal method, which are authorized by the manufacturer of endoscopic equipment.

      After completion of pre-sterilization cleaning combined with disinfection, the quality of the cleaning is checked; in accordance with operating instructions, functional tests are carried out, the image quality is checked, cranes and articulated mechanisms of the endoscope’s moving parts are lubricated.

      Before the automatic sterilization cycle, the endoscope is thoroughly dried and placed in the sterilization container recommended for the chosen sterilization method.

      The process of manual sterilization of the endoscope is similar to the process of sterilization of flexible endoscopes for sterile endoscopic interventions.

      The treatment of a camera control unit and a video head unit (a video head unit with an integrated optical adapter (lens), a video head with a screw connection and with or without an optical adapter, as well as the optical adapter itself) begins immediately after a network plug is disconnected.

      The video camera control unit is wiped with a disposable cloth moistened with a disinfectant that does not contain aldehydes, alcohols or other components that fix biological contamination.

      The video head, lens and cable of the video head, after visual check for the presence of gaps and cracks, are pre-cleaned in the solution of a neutral detergent.

      The process of pre-sterilization cleaning combined with disinfection of endoscopic equipment includes the following steps:

      immersion in washing-disinfecting solution for the period of disinfection exposure;

      removal of dirt from the video head and lens with a soft brush (cloth);

      rinsing with distilled water.

      Endoscopic equipment is sterilized in accordance with the manufacturer’s recommendations using steam, gas or plasma methods. Before sterilization, the purity of the optics and camera plug is checked, glass surfaces are dried with 70% alcohol, and inspection for damage is carried out.

      Before using disposable sterile covers to improve the safety of the video head and cable during a surgical intervention, these medical devices undergo all treatment procedures in accordance with the manufacturer’s instructions.

      Pre-sterilization cleaning, combined with disinfection, of fiberglass (liquid) light guides is carried out manually or mechanically. Before sterilization, glass surfaces are additionally dried with 70% alcohol, and a functional test is carried out. Fiberglass fibers are sterilized by:

      steam, gas and plasma methods;

      solutions of aldehyde-containing, active oxygen and some chlorine-containing agents in sporicidal concentration. Liquid fibers are sterilized by the gas method or in solutions of chemical agents.

      Pre-sterilization cleaning combined with disinfection of an aspiration jar and a set of reusable silicone tubes, which are accessories to the aspiration (rinsing) pumping unit or pump, after each endoscopic operation is carried out manually or mechanically, sterilization is performed by the steam method recommended by the manufacturer.

      After disconnecting from the network, the pump is wiped with a cloth moistened with an alcohol-free disinfecting solution.

      The treatment of an insufflation device with accessories is carried out in the following sequence: after disconnecting from the network, the device is wiped with a disposable cloth moistened with an alcohol-free disinfecting solution. Used disposable antibacterial CO2-gas filters are classified as class B medical waste;

      a set of reusable silicone tubes is exposed to:

      pre-cleaning in a solution of detergent;

      pre-sterilization cleaning combined with disinfection, manually or mechanically using special tools for unhindered washing of internal cavities of the tubes with a stream of detergent-disinfectant; manual treatment requires mechanical cleaning of hollow spaces with brushes;

      rinsing with distilled water;

      drying of internal cavities with air and outer surfaces - with a cloth;

      inspection and leak test;

      steam sterilization.

      A set of tubes for arthroscopy is used once and cannot be re-treated.

      When preparing endoscopic equipment for surgical endoscopic interventions, in order to prevent infection of patients and contamination of the device, a disposable sterile antibacterial CO2-gas filter is installed on the insufflation connector for each operation.

      The shelf life of sterilized endoscopes and their instruments is determined by the chosen sterilization method, type and shelf life of the packaging material.

 **14. Requirements for premises of structural units of health facilities intended for carrying**
**out sterile endoscopic interventions, treating endoscopes for sterile**
**interventions and instruments**

      Sterile endoscopic interventions are performed in surgery rooms, small surgery rooms of health facilities or in endoscopic manipulation rooms of specialized surgical departments.

      Pre-cleaning of endoscopic equipment (rigid endoscope, camera head, light guide, aspiration (flushing) pump, insufflation device, a set of silicone tubes, tools) after the completion of surgery, is performed in the area in which the surgical equipment is pre-cleaned.

      Pre-cleaning of flexible endoscopes and their instruments is carried out immediately after completion of an intervention in the endoscopic manipulation room.

      Pre-sterilization cleaning, combined with disinfection, of endoscopes for sterile manipulations and instruments is performed in the room for disassembling and washing the instruments of the surgical unit, in the washing and disinfection room of the surgical department, in the CSD.

      Endoscopes for sterile interventions and their instruments are sterilized:

      manually in the sterilization room (class “B” cleanliness) of the operating unit or surgical department;

      mechanically with the use of sterilization equipment in the sterilization room (class “B” cleanliness) of the surgical unit, surgical department, CSD.

      Endoscopes and instruments subjected to sterilization are stored under aseptic conditions.

      Cleaning and disinfection in rooms, where sterile endoscopic interventions are carried out, shall be after each intervention.

      Overall cleaning shall be once a week.

 **15. Procedure for conducting epidemiological investigation of cases of infectious**
**diseases presumably associated with endoscopic interventions**

      In case of an infectious disease, presumably associated with endoscopic intervention, an epidemiological investigation shall be carried out.

      When investigating a case of infection caused by pathogenic bacteria:

      it is necessary to fix the date of the disease, the results of bacteriological examination of clinical material with characteristics of the isolated strain of the microorganism, serological and other laboratory research methods; the date (or dates) of the endoscopic intervention within the incubation period of the disease;

      the health facility’s units performing endoscopic interventions are inspected to assess: the compliance of endoscopes’ actual treatment with the requirements of these Sanitary Rules; used cleaning and HLD agents; the ensuring of control of HLD cycle parameters; the quality of pre-sterilization cleaning and sterilization of instruments; knowledge of the personnel that treated the endoscopes, whether they have certificates of advanced training in the prevention of infections associated with endoscopic interventions;

      the results of scheduled bacteriological monitoring of the efficiency of the treatment of endoscopes over a year preceding the epidemiological investigation are analyzed.

      To identify the presumed source of infection and patients who were at the same risk of infection as the aggrieved person, the following measures are taken:

      a hospital makes a list of patients who were examined (operated) before and after the aggrieved patient with the same endoscope, within the time specified by the epidemiologist in accordance with the etiology of the disease on the basis of the register of examinations performed in a department, unit, endoscopic room, a log of surgical interventions;

      the infectious status of patients included in the above list is determined according to medical records and additionally conducted laboratory tests;

      health workers who directly participated in the aggrieved patient’s endoscopic intervention and in the treatment of the equipment are subject to examination and laboratory examination;

      a direct connection is revealed between the aggrieved person (persons) and the presumed source of infection (if identified) by proving the identity of bacteria of the same species, isolated from clinical material, using culture-based (species identification with the definition of an antibiogram), and, where possible, molecular genetic methods of laboratory examinations.

      An endoscope, its instruments, a WDM, hands of medical personnel are considered as probable factors of transmission of the pathogen.

      To identify the factor of transmission of the pathogen, the following measures are taken:

      assessment of the leakproofness of the endoscope, which was used to examine the aggrieved person, and an extraordinary bacteriological control of the efficiency of its treatment with identification of the type of isolated microorganisms. Isolation from washings taken from the channels and (or) from the endoscope’s external surfaces, a microorganism identical to the infectious disease pathogen in the aggrieved person indicates that this endoscope was the factor of infection transmission;

      the type of an instrument used is determined according to the endoscopic examination protocol; compliance with the treatment technology, including sterilization method, is assessed; previous results of scheduled microbiological control of instruments for sterility are analyzed; unscheduled bacteriological control is carried out;

      a WDM is detected (in case of mechanical treatment), in which the endoscope was treated and bacteriological examination of washings from different parts of the machine and samples of the working solution of a disinfectant (with repeated use) for secondary contamination is carried out. Isolation of the microorganism from selected samples identical to the infectious disease pathogen in the aggrieved person will give reason to consider the WDM as a factor of infection transmission.

      Investigation of cases of infections caused by opportunistic pathogenic bacteria (hereinafter referred to as OPB) and related to diagnostic endoscopic examinations or surgical interventions performed by endoscopic access is carried out by analogy with infections caused by pathogenic bacteria. Additionally, data on the epidemic situation and results of microbiological monitoring of the health facility as a whole are assessed. Infections caused by OPB are subject to registration if they occur between 48 hours and 30 days of the date of the endoscopic intervention.

      To determine the identity of cultures of bacteria of the same type, isolated from clinical material from infected patients, as well as in washings with presumed factors of infection transmission, their culture-based properties, antibiograms are compared, and, if possible, molecular genetic methods are used.

      In case of epidemiological investigation of a patient’s infection with the hepatitis B virus (hereinafter referred to as HBV) or the hepatitis C virus (hereinafter referred to as HCV), presumably associated with endoscopic intervention, it is necessary to collect the following patient data: the date of the disease, the date of the most recent, preceding the disease, examination of blood serum for markers viral hepatitis and (or) detection of deoxyribonucleic acid (hereinafter referred to as DNA) and (or) ribonucleic acid (hereinafter referred to as RNA) with a documented negative result; availability of hepatitis B vaccination (dates of administration of the vaccine and the drug); the date (dates) of the endoscopic intervention within the maximum incubation period.

      When considering the endoscope as a likely factor of transmission of the pathogen, the following measures are taken:

      all aspects of the treatment of endoscopes are studied in accordance with these Sanitary Rules;

      a map of endoscopic interventions (the sequence of different types of interventions performed) is drawn up and, according to the register of examinations performed in a department, unit, endoscopic room, or using a log of surgical interventions in the hospital, patients are identified who, for 3 months (for HBV) or 2 weeks (for HCV) before the date of endoscopic intervention of an infected patient were examined (operated) with the same endoscope;

      medical records of identified patients are being studied to obtain data on the presence (absence) of hepatitis B (C) in them before being admitted to a health facility; persons, who do not have this information, are subjected to additional examination for HBV (HCV) markers, DNA (RNA) detection and the genotype of the virus.

      A patient, whose hepatitis virus of the same genotype as that of the aggrieved person was identified before the endoscopic examination date, is considered to be the presumed source of infection. To prove his/her direct connection with the victim, molecular genetic testing of viruses is carried out to determine their identity.

      Patients without identified markers of viral hepatitis (seronegative patients) within the period specified above are considered as persons at risk of infection along with the aggrieved person. Identification of HBV (HCV) markers in them within the maximum incubation period after endoscopic examination is the basis for in-depth clinical and laboratory examination using molecular genetic virus verification methods to confirm (exclude) the connection with the source of infection and the infected patient.

      If endoscopic examination was carried out with the use of sedatives, the name of the drugs and their packaging (single-dose, multi-dose) are found out. When using one vial of the drug for the patient and other patients (regardless of the type of endoscopic examination performed), their blood is tested for HBV (HCV) markers, and in seropositive persons - isolation of DNA (RNA) viruses is performed. In order to prove the connection between patients infected with a single genotype virus, molecular genetic research methods are additionally used.

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|   | Appendix 10 to Sanitary Rules“Sanitary and epidemiologicalrequirements for the organizationand conduct of disinfection, pestand rodent control” |

 **Rodents’ count**

      1. Rodents are counted twice a year to assess the state of the populations of rats and mice during their breeding period – in March-April and in October-November, before rodents enter from open stations into buildings during the period their numbers are largest.

      The count is carried out in two stages. For the first preliminary assessment of the density of colonization of buildings by rodents, all buildings occupied at the time of the count are taken into account.

      2. At the first stage, for preliminary assessment of the density of colonization, it is necessary to use the sites of flour bait or talcum, which buildings have inside, and if they are not enough, new sites shall be placed. In buildings up to 1000 m2, the sites are placed along the walls every 4–5 meters, and in buildings of a larger area - less often, every 8–10 meters. Sites are not placed throughout the entire area of ​​buildings, but only in those rooms where rodents are most likely to be found: in basements, undergrounds, storerooms, outbuildings, food facilities, first and second floor apartments, and in case of the count of black rats – also in attics. The density of colonization is determined by dividing the number of all sites visited by rodents by the total area of those buildings where their traces were found, and are assessed according to the following scale:

|  |
| --- |
|
Rodents’ visits of sites per 1,000 m2 of buildings colonized by them  |
|
A lot |
Moderately |
Few |
|
Over 5.0 |
5.0-1.0 |
Less than 1.0 |

      Example:

      17 sites

      X = ------------ = 1.7 (moderately)

      10.0 thousand m2

      3. The second stage of the count is carried out with the help of mashers in all the rooms, where traces were found, when taking the sites into account. In rooms colonized by rats, one rat trap is placed for every 20 m2, and 1 mouse trap per 10 m2 in the rooms colonized by mice. In rooms, where traces of rodents were not detected, traps are not set. For three days in a row, all mashers are inspected once a day, caught rodents are collected, the eaten bait (bread with vegetable oil) is replenished. The number of each species of rodents is determined separately as follows: the total number of caught animals of one species is divided by the total area of technical buildings where these animals were caught.

      1. The number of each species is estimated on a scale:

|  |
| --- |
|
Animals caught per 1,000 square meters of buildings colonized by them  |
|
A lot |
Moderately  |
Few  |
|
Over 1.0 |
1.0-0.5 |
Less than 0.5 |

      Examples:

      5 brown rats

      X, = ------------- = 0.8 brown rats per 1,000 m2 (moderately)

      6.1 thousand m2

      9 house rats

      Х2= --------------- = 0.6 house rats per 1,000 m2 (moderately).

      14.6 thousand m2

      4. In open stations, they are counted before the migration of rodents into buildings to determine the state of the population of rats, mice, and other species outside the buildings and to take measures to protect buildings from rodent invasion from the outside. Prior to their counting, open area plots are examined visually, and places are marked for linear alignment of mashers separately for rats and mice.

      5. The number of places for counting is determined as follows: 100 mashers per day (one hundred trap-days) for every 5 hectares of open territory to be surveyed. In a populated locality not divided into districts, or in each district of a large city, the counting is carried out in two or three places (200-300 trap-days). Mashers are placed in line at a distance of 5 m from each other, in the afternoon or in the evening, and early in the morning they are inspected and rodents are removed. It is allowed to set 50 mashers for 2 days, with their inspection in the mornings of the first and second days of counting. After the first inspection, the bread bait in the traps is replaced with fresh one.

      6. The number of animals of each species (percentage of catching) is determined using the formula:

      Total number of caught rodents х 100

      Х = ----------------------------

      Total number of trap-days

      Example:

      8 brown rats х 100 =800

      X = ----------------------- = 2.7 brown rats per 100 trap-days

      150 traps х 2 days = 300

      7. The comparison of the obtained results with the data of previous counts allows determining the decrease or increase in the number of this species.

|  |  |
| --- | --- |
|   | Appendix 2 to Order №ҚР ДСМ-8 of the Minister ofHealthcare of the Republic ofKazakhstan as of August 28, 2018  |

 **List of some invalidated orders of the Minister of National**
**Economy of the Republic of Kazakhstan**

      1) Order № 48 of the Minister of National Economy of the Republic of Kazakhstan as of January 27, 2015 “On Approval of Sanitary Rules “Sanitary and epidemiological requirements for the organization and conduct of disinfection, pest and rodent control” (registered in the Register of State Registration of Regulatory Legal Acts under № 10388, published in the “Adilet” Legal Information System on April 10, 2015);

      2) paragraph 1 of the list of some orders of the Minister of National Economy of the Republic of Kazakhstan subject to amendments, which is approved by Order № 389 of the Minister of National Economy of the Republic of Kazakhstan as of August 29, 2016 “On Amendments to Some Orders of the Minister of National Economy of the Republic of Kazakhstan” (registered in the Register of State Registration of Regulatory Legal Acts under № 14308, published in electronic form in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan on October 26, 2016);

      3) subparagraph 1) of paragraph 1 of Order № 677 of the Minister of National Economy of the Republic of Kazakhstan as of October 23, 2015 “On Amendments to Some Orders of the Minister of National Economy of the Republic of Kazakhstan” (registered in the Register of State Registration of Regulatory Legal Acts under № 12333, published in the “Adilet” Legal Information System on December 28, 2015).

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