

21 NCAC 19 .0404 DEFINITIONS AND OVERVIEW

In addition to the terms defined in G.S. 88-A, the following terms have the following meanings:

- (1) "Alcohol-based hand rub or gel" is a preparation which contains 60 percent to 95 percent ethanol or isopropanol that is designed for application to the hands in order to reduce the number of viable microorganisms on the hands.
- (2) "Antiseptic" is a germicide used on skin or living tissue to inhibit or destroy microorganisms.
- (3) "Aseptic technique" is the term used to describe the precautionary measures taken to help reduce the risk of post treatment infections by decreasing the opportunity for microorganisms to enter the body. Precautionary measures include handwashing, disinfection, sterilization of surfaces and instruments, use of protective barriers, containment and disposal of waste, and instrument and surface manipulations that minimize cross contamination.
- (4) "Autoclave" is a vessel used for sterilization by the application of saturated steam under pressure and heat.
- (5) "Biological indicator" is a commercially prepared device populated with bacterial spores which is used to test the method of sterilization being monitored and which demonstrates whether or not conditions necessary to achieve sterilization were met during the cycle being monitored.
- (6) "Chemical indicator" is a chemically treated paper strip used to monitor parameters of a heat sterilization process by means of a characteristic color change. A chemical indicator does not indicate that sterilization has been achieved, but rather, that the temperature needed has been attained.
- (7) "Cleaning" is the removal of all visible organic material from objects using friction, detergent and water prior to the disinfection and sterilization processes.
- (8) "Contaminate" is to make something impure by exposure to or addition of a polluting substance.
- (9) "Contaminated" is the presence of potentially infectious pathogenic microorganisms on surfaces of a objects.
- (10) "Cross-contamination" is the process by which bacteria or other microorganisms are transferred from one substance or object to another, with harmful effect.
- (11) "Critical items" are instruments, devices, objects or environmental surfaces that will come in direct contact with the bloodstream or other normally sterile areas of the body.
- (12) "Decontaminate" is to neutralize or remove dangerous substances or germs from an area or object.
- (13) "Decontamination" is the use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item so that they are no longer capable of transmitting infectious particles and to render the surface or item safe for handling, use, or disposal.
- (14) "Disinfect" is to clean with a disinfectant in order to destroy bacteria.
- (15) "Disinfectant" is a chemical agent used on inanimate surfaces and objects to destroy infectious fungi and bacteria, but not necessarily their spores and is classified into levels of potency as follows:
 - (A) High-level, which is utilized for the reprocessing of semi-critical instruments or devices and includes Food and Drug Administration (FDA) regulated substances such as glutaraldehyde-, chlorine dioxide-hydrogen peroxide, orthophthaldehyde-, and peracetic acid-based formulations;
 - (B) Intermediate-level, which is utilized for disinfecting tips for epilator needles and includes Environmental Protection Agency (EPA) regulated substances such as alcohols containing 70 to 90 percent ethanol or isopropanol, chlorine compounds, and certain phenolic or iodophor preparations as determined by the EPA;
 - (C) Low-level, which is utilized for disinfecting environmental or non-instrument surfaces and includes EPA regulated substances such as quaternary ammonium compounds and certain phenolic or iodophor preparations as determined by the EPA.
- (16) "Disinfection" is a procedure that reduces the level of microbial contamination and is classified into the following levels:
 - (A) "High-level," which inactivates some, but not necessarily all, bacterial spores. This process will also kill *Mycobacterium tuberculosis* var.

- bovis, and all microorganisms with the exception of high levels of bacterial spores.
- (B) "Intermediate-level," which does not kill bacterial spores, but is capable of killing. *M. tuberculosis* var. *bovis*, most vegetative bacteria and fungi, as well as viruses such as hepatitis B virus (HBV) and human immunodeficiency virus (HIV);
 - (C) "Low level," which inactivates most bacteria, some viruses and fungi but not bacterial spores or *Mycobacterium tuberculosis* var. *bovis*.
- (17) "Dry heat sterilizer" is a forced air oven-type device designed to sterilize items by exposure to high temperatures for designated exposure periods.
 - (18) "Environmental surfaces" are surfaces in the electrology treatment room which may potentially contribute to cross-contamination by hands of the electrologist or by contact with instruments that will subsequently come into contact with clients.
 - (19) "Enzyme detergent" is the detergent that helps break down organic soils and fats, and suspends particles during cleaning. An enzyme detergent is used as a soaking solution for critical and non-critical instruments and as the detergent used in the ultrasonic device.
 - (20) "Epilator" is an electrical device used to perform electrolysis.
 - (21) "Epilator cords" are insulated plastic covered cords used to complete the current circuit between the epilator and the epilator needle or the indifferent electrode.
 - (22) "Forceps" are the instruments or "tweezers" used in electrology treatments to lift the treated hair from the follicle. Forceps used in electrology are not intended to be critical items, but may come in contact with blood, serum or other material and shall be sterile when used.
 - (23) "Gloves" are coverings for the hands, which provide a protective barrier against infections and toxic substances.
 - (24) "Hand hygiene" is the general term that applies to:
 - (A) "Hand washing," the decontamination process for the removal of soil and transient microorganisms from the hands by a vigorous rubbing together of all surfaces of lathered hands for at least 15 seconds, followed by rinsing under a stream of water;
 - (B) "Antiseptic hand wash," the washing of hands with water and soap or other detergents containing an antiseptic agent;
 - (C) "Antiseptic hand rub," the application of an alcohol-based hand rub product, to all surfaces of the hands to reduce the number of microorganisms present; and
 - (D) "Hand antisepsis," a preoperative antiseptic hand wash or antiseptic hand rub to eliminate transient microorganisms and reduce resident hand flora.
 - (25) "Health History Assessment File" is a cumulative and permanent documentation of a client's medical and treatment record which is maintained by the electrologist.
 - (26) "Hirsute or Hirsutism" is the excessive growth of hair that is thickened caused by hormonal or biochemical imbalances or genetic predisposition.
 - (27) "Hospital-grade disinfectant" is a chemical germicide that is classed in a spectrum of activity as either low-level or intermediate-level, with labeled claims for effectiveness against *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.
 - (28) "Indifferent electrode" is a stainless steel bar held by the client during electrology treatments to complete current circuit with galvanic electrolysis modality or with the use of a timer delay switch in automatic delivery epilators.
 - (29) "Instruments" are tools or devices designed to perform a specific function, such as grasping, holding, or retracting.
 - (30) "Intact skin" is skin in which the natural protective barrier has not been altered by infection or trauma.
 - (31) "Latex allergy" is a systemic or local allergic response to various latex proteins to which the individual has been sensitized.
 - (32) "Medical-grade gloves" are disposable gloves used during medical examinations and procedures to prevent contamination between caregivers and patients.
 - (33) "Microbial" is a minute life form; a microorganism, especially a bacterium that causes disease.

- (34) "Nitrile" is non-sterile, latex-free substance from which gloves are manufactured.
- (35) "Needle" is the pre-sterilized, disposable wire filament which is inserted into the hair follicle for application of current in electrology.
- (36) "Non-critical items" are instruments, devices, objects or environmental surfaces that will come in contact only with intact skin.
- (37) "Non-intact skin" is skin in which there is a break in the skin's natural integrity, for example, exposed skin that is chapped, abraded, or afflicted with dermatitis.
- (38) "Packaging" is a generic term meant to include all types of containment, such as woven or non-woven wraps, paper or film pouches, or rigid container systems.
- (39) "Pathogen" is a microorganism or substance capable of producing a disease.
- (40) "Phoresis rollers" are sterilized stainless steel rollers used to apply current to skin before or after electrology treatment.
- (41) "Physical visible indicators" are monitoring devices built into a sterilizer, such as indicating thermometers, recording thermometers, pressure gauges and automatic controls, which are used in identifying and preventing malfunctions and operational errors and for recordkeeping purposes.
- (42) "Plain soap" is a detergent-based cleanser without antimicrobial additives which is used for the physical removal of dirt and transient microorganisms.
- (43) "Protective disposable barrier" is a disposable, moisture-resistant covering which reduces the potential for contaminating environmental or medical device surfaces that may be difficult or inconvenient to clean and disinfect routinely, for example, tables and pillows, or hard-to-clean surfaces such as light handles and epilator surfaces..
- (44) "Reprocessing" is the process of cleaning, disinfecting or sterilizing a reusable instrument that has been used or contaminated in order to be made safe for its intended use.
- (45) "Semi-critical items" are instruments, devices, objects or environmental surface that may come in contact with mucous membranes and non-intact skin, but do not ordinarily penetrate body surfaces. Semi-critical items require sterilization or exposure to high-level disinfection as set in Item 44 of this Rule.
- (46) "Sharps container" is a manufactured and labeled, leak-proof, rigid, puncture-resistant, durable plastic container into which needles are placed after use and which is designed to be disposed of as an item of regulated medical waste.
- (47) "Standards" is the level of quality or excellence.
- (48) "Sterility assurance file" is the record containing the sterilizer maintenance and use log and culture report from each biological monitor.
- (49) "Sterilization" is the process which destroys all forms of microbial life. The recommended methods of sterilization of instruments and items used in the practice of electrology are the dry heat sterilizer or the autoclave.
- (50) "Tip for epilator needle" is the cap or plastic tip that surrounds the base of the needle and covers the pin device where the needle shank is seated.
- (51) "Treatment room" is the operatory where electrolysis treatments are performed.
- (52) "Ultrasonic cleaner" is a processing unit using ultrasonic waves transmitted through the cleaning solution in a mechanical process known as cavitation. The transmitted sound waves produce tiny air bubbles on instrument surfaces, which scrub tightly adhering or embedded particles from solid surfaces and remove soil deposits from hard-to-reach areas.

History Note: Authority G.S. 88A-6; 88A-16;
Eff. December 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.