

**21 NCAC 19 .0407      CLEANING, STERILIZATION, AND SAFETY PRECAUTIONS FOR INSTRUMENTS AND OTHER TREATMENT-RELATED ITEMS**

- (a) Each office of each electrologist and laser hair practitioner shall be inspected by the Board or its agent:
  - (1) prior to initial licensure;
  - (2) each time an office is relocated;
  - (3) annually after a license is issued; and
  - (4) at any time the Board deems necessary to ensure safety of the public, including in response to a complaint or inquiry.
- (b) Electrologists shall observe the following safety precautions for the cleaning and sterilization of instruments:
  - (1) Coordinate sterilized instruments and supplies needed for each treatment in a manner whereby adherence to aseptic technique is maintained;
  - (2) Wear gloves when handling soiled instruments; and
  - (3) Avoid puncture injury from instruments.
- (c) As used in this Rule, instruments and other items include:
  - (1) Needles that are:
    - (A) single-use, pre-sterilized, and disposable;
    - (B) stored in a manner that will maintain sterile conditions of contents;
    - (C) not recapped, bent, or otherwise manipulated by hand prior to disposal;
    - (D) placed in a puncture-resistant sharps container after use, when opened or found damaged, when contaminated before use, or when not used before pre-printed expiration date; and
    - (E) disposed of in accordance with State and local regulations when the sharps container is no more than three quarters full;
  - (2) Forceps, phoresis rollers, and epilator tips that are:
    - (A) disinfected before initial use and after use on the client;
    - (B) disinfected after a 24-hour period when packaging is opened and instruments are unused or when packaging is contaminated before use, for example, dropped or placed on a surface not protected by barriers;
    - (C) accumulated after use and before cleaning and sterilization in a covered holding container by submersion in a solution of a protein-dissolving enzyme detergent and water, following manufacturer's instruction for dilution, then rinsed and drained; and
    - (D) cleaned and sterilized in accordance with the standards in Paragraphs (d) and (e) of this Rule.
- (d) Electrologists shall observe the following standards for cleaning:
  - (1) Place items and other instruments in the basket of a covered ultrasonic cleaning unit containing a fresh solution of a protein-dissolving enzyme detergent and water;
  - (2) Follow manufacturer's instructions for dilution and ultrasonic running times;
  - (3) Remove basket from ultrasonic unit rinse under running water and drain;
  - (4) Drain and air dry items on a clean, disposable, absorbent, non-shedding cloth in an area protected from exposure to contaminants with a hot-air dryer or by placement into a drying cabinet;
  - (5) Package forceps, rollers, and heat-stable tips individually in woven or non-woven wraps, paper or film pouches, or rigid container systems for the sterilization process;
  - (6) Place packaged instruments and items in an autoclave or dry-heat sterilizer with a chemical indicator;
  - (7) If dry-heat sterilizers are used, subject the heat-sensitive tips to an intermediate-level disinfectant, after which the tips are rinsed and dried; and
  - (8) Store instruments and items in a clean and dry covered container, drawer or closed cabinet after the cleaning process.
- (e) Electrologists shall observe the following standards for sterilization:
  - (1) The required minimum time and temperature relationship for sterilization methods shall be:
    - (A) for the dry heat method, the minimum time-temperature relationship required to be attained is 340° F (170° C) for one hour or 320° F (160° C) for two hours; and
    - (B) for the autoclave (steam under pressure) method, the minimum time-temperature-pressure relationship required to be attained is 15 to 20 minutes at 121°C (250°F) and 15 psi (pounds per square inch) for unpackaged instruments and items and 30 minutes at 121° C (250° F) and 15 psi (pounds per square inch) for packaged instruments and items.

- (C) temperature and exposure requirements in Parts (A) and (B) of this Subparagraph relate to the time of exposure after attainment of the required temperature and do not include a penetration of heat-up lag time, drying time, or cool-down time;
  - (2) Sterilizers shall have visible physical indicator gauges, for example, thermometers, timers, on the devices that shall be monitored during the sterilization cycle;
  - (3) The interior of the sterilization devices shall be cleaned according to the manufacturer's instructions;
  - (4) Packaging for sterilization shall:
    - (A) accommodate the size, shape, and number of instruments to be sterilized;
    - (B) be able to withstand the physical conditions of the selected sterilization process;
    - (C) allow enough space between items in each package for the sterilization of all surfaces to occur; and
    - (D) chemical indicators shall be visible on the outside of each package sterilized that indicates the instruments and items have been exposed to a sterilization process.
  - (5) Manufacturer's recommendations shall be followed for aseptic removal of contents in the sterilized packages;
  - (6) Biological monitors shall be used no less than once a month for each sterilization device according to manufacturer's instruction in order to ensure that proper mechanical function of the sterilizer is maintained; and
  - (7) Recorded laboratory reports from the biological monitors shall be filed in a permanent sterility assurance file.
- (f) Safety precautions shall be observed for other treatment related items as follows:
- (1) Indifferent electrodes, epilator cords, and eye shields shall be cleaned, dried, and subjected to intermediate-level disinfection before initial use and after each treatment and replaced when showing signs of wear and tear;
  - (2) Ultrasonic cleaning units and all other containers and their removable parts shall be used during soaking and cleaning procedures, cleaned, dried daily, and used and maintained according to manufacturer's instructions; and
  - (3) Environmental surfaces directly related to treatment shall be cleaned and subjected to low-level disinfection daily and whenever visibly contaminated.

*History Note: Authority G.S. 88A-6(9); 88A-16;  
Eff. December 1, 2010;  
Amended Eff. September 1, 2015;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.*