21 NCAC 06V .0105 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;*
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