

CHAPTER 64B5-25 STERILIZATION AND DISINFECTION PROCEDURES

64B5-25.001	Purpose.
64B5-25.002	Definitions.
64B5-25.003	Required Sterilization and Disinfection Procedures.
64B5-25.004	Licensees Infected With Hepatitis B Virus.
64B5-25.005	Monitoring of Licensees Infected With the Hepatitis B Virus.
64B5-25.006	Emergency Suspension of Licensees Infected With the Hepatitis B Virus; Initiation of Complaints.
64B5-25.007	Disposition of Biohazardous Waste.
64B5-25.008	Shipment to Dental Laboratories.

64B5-25.001 Purpose.

The failure to follow proper sterilization and disinfection procedures in the practice of dentistry presents a significant danger to the public due to the potential for transmission of infectious diseases to patients during treatment. Failure to follow proper sterilization and disinfection procedures as set forth in Rule 64B5-25.003, F.A.C., constitutes failure to provide reasonable sanitary facilities and conditions in violation of Section 466.028(1)(u), F.S., and constitutes negligence in the practice of dentistry in violation of Section 466.028(1)(x), F.S., as practice which is below the minimum standards of the practice of dentistry.

Specific Authority 466.004(4) FS. Law Implemented 466.028(1)(u), (x) FS. History—New 2-24-87, Formerly 21G-25.001, 61F5-25.001, 59Q-25.001.

64B5-25.002 Definitions.

- (1) “Sterilization” is defined to mean the process by which all forms of life within an environment are totally destroyed.
- (2) “Disinfection” is defined to mean the destruction or inhibition of most pathogenic bacteria while they are in their active growth phase and the inactivation of some viruses. Disinfection allows the potential for viable pathogens to remain (e.g., Tubercle bacilli and some viruses, including A, B and C hepatitis virus, and nonA-nonB (NANB) viruses which may survive depending upon the chemicals used).
- (3) For purposes of this rule, the term “infected with the Hepatitis B virus” means that the licensee is seropositive for the Hepatitis B surface antigen and the Hepatitis B e-antigen.

Specific Authority 466.004(4) FS. Law Implemented 466.028(1)(u), (x), 466.041 FS. History—New 2-24-87, Amended 1-7-92, 2-1-93, Formerly 21G-25.002, 61F5-25.002, 59Q-25.002, Amended 5-20-01.

64B5-25.003 Required Sterilization and Disinfection Procedures.

- (1) At least one of the following procedures must be used in order to provide proper sterilization:
 - (a) Steam under pressure (e.g., autoclave);
 - (b) Dry-heat;
 - (c) Chemical vapor;
 - (d) Ethylene oxide;
 - (e) Disinfectant/sterilant. U.S. Environmental Protection Agency (EPA) approved disinfectant/sterilants or U.S. Food and Drug Administration (FDA) approved sterilant may be used but are only appropriate for sterilization when used in appropriate dilution and for the time periods set forth in the manufacturer’s recommendation and only on non-heat tolerant instruments which do not penetrate soft tissue.
- (2)(a) Surgical and other instruments that normally penetrate soft tissue or bone, including, but not limited to, forceps, scalpels, bone chisels, scalers, and surgical burs, must be sterilized after each use.
- (b) Instruments that are not intended to penetrate oral soft tissue or bone, including, but not limited to, high speed dental handpieces, contra-angles, prophylaxis angles, amalgam condensers, plastic instruments, and burs, but that may come into contact with oral tissues must be sterilized after each use.
- (c) However, if heat, steam under pressure, or chemical vapor sterilization of an instrument is not technically feasible, due to its size or composition, the instrument must undergo sterilization with a disinfectant/sterilant that destroys viruses and spores. Disinfectants must be registered by the U.S. Environmental Protection

Agency (EPA) as a disinfectant/sterilant and must be used in accordance with the manufacturer's recommendations and the recommendations of the Centers for Disease Control (CDC).

(d) High speed dental handpieces, slow speed dental sleeves and contra-angles and prophylaxis angles must be sterilized after each use using a heat or heat with pressure or heat with chemical method. The method used must be capable of sterilization.

(e) Heat-sensitive instruments may require up to 10 hours of exposure in a liquid chemical agent registered by the U.S. Environmental Protection Agency (EPA) as a disinfectant/sterilant.

(3) Before sterilization, instruments must be cleaned to remove debris. Cleaning must be accomplished by a thorough scrubbing with soap or a detergent and water or by using a mechanical device, such as an ultrasonic cleaner following the manufacturer's recommendations. Metal or heat-stable dental instruments must be sterilized after each use by one of the procedures identified in paragraphs (a)-(d) of subsection (1) above.

(4) Oral prosthetic appliances received from a dental laboratory must be washed with soap or a detergent and water, rinsed well, appropriately disinfected and rinsed well again before the prosthetic appliance is placed in the patient's mouth.

(5) At the completion of dental treatment, all surfaces that may have become contaminated with blood, saliva or other bodily fluids must be disinfected using a procedure recommended by the Centers for Disease Control (CDC).

(6) Disinfectant/sterilants appropriate for use under paragraph (e) of subsection (1) above are only those disinfectant/sterilants that are registered by the EPA. Those disinfectant/sterilants must be used in accordance with the manufacturer's recommendations for correct use as a disinfectant/sterilant.

(7) The sterilization and disinfection procedures required by this rule must be followed unless appropriate disposable items are used. Disposable items may only be used on a one time basis and may never be used on more than one dental patient. The use of disposable items is encouraged.

(8) Surgical or examination gloves and surgical masks shall be worn by all dentists, dental hygienists, and dental assistants while performing or assisting in the performance of any intra-oral dental procedure on a patient in which contact with blood and/or saliva is imminent. Surgical or examination gloves must be changed between patients. Hands shall be washed with soap and water and dried immediately after removing and prior to replacing gloves. Gloves are never to be washed and reused. Surgical or examination gloves that are punctured or torn must be removed and replaced immediately with new gloves following rewashing of provider's hands with soap and water. It is recommended that eye protection be worn by all dentists, dental hygienists, and dental assistants while performing or assisting in the performance of any dental procedure on a patient in accordance with CDC recommendations.

(9) The procedures and equipment used for sterilization must have their efficacy tested periodically. Adequacy of steam under pressure (e.g. autoclave) or chemical vapor sterilization must have their efficacy verified by appropriate biological monitoring at least once every 40 hours (2400 minutes) of use or at least once every thirty days, whichever comes first. Dry heat and ethylene oxide sterilizers must have their efficacy verified with appropriate biological monitoring every 120 hours of operation at sterilization parameters or every thirty days, whichever comes first. (Use time is determined by multiplying the number of cycles by the individual cycle time.) Disinfectant/sterilants as set forth in paragraph (e) of subsection (1) above, when used instead of heat sterilization procedures, must be used according to the manufacturer's recommended dilution and exposure time and must be changed according to the manufacturer's recommendations.

(10) All OSHA category 2 employees must be provided with and must use the barrier techniques required by this rule when they are in situations where they may be exposed to blood, saliva, or other bodily fluids from the patient during the treatment or examination process.

Specific Authority 456.032, 466.004(4) FS. Law Implemented 456.032, 466.028(1)(u), (x), 466.041 FS. History—New 2-24-87, Amended 12-6-87, 10-24-88, 1-7-92, 4-5-93, Formerly 21G-25.003, Amended 11-22-93, Formerly 61F5-25.003, 59Q-25.003, Amended 10-31-01, 3-19-02.

64B5-25.004 Licensees Infected With Hepatitis B Virus.

(1) The Board of Dentistry is charged with the responsibility of protecting the public from dentists or dental hygienists who present a danger to the public. The Board finds that licensees who are infected with the Hepatitis B virus present a grave danger to the public by virtue of the communicability of this infectious disease in a clinical setting. Absent the identification of infected licensees and the implementation of proper barrier techniques, these practitioners represent an unacceptable risk to the health and safety of their patients.

Licensees bear the ultimate responsibility for the safety of their patients when the licensee or personnel employed by the licensee represent a health risk through direct or indirect contact with patients. This rule assures the ability of infected licensees to practice so long as adequate safeguards are maintained.

(2) Any Florida licensed dentist or dental hygienist practicing in this State who is infected with the Hepatitis B virus is required to notify the Board of such in writing no later than 14 days after learning of his or her infection with the Hepatitis B virus. Such notice shall include a copy of the lab report showing the result of that dentist's or dental hygienist's Hepatitis B Surface Antigen (HBSAG) test results. The Board will respond to the licensee in writing acknowledging the notification and will provide the licensee with an outline of criteria to be complied with which are designed to limit the potential spread of the virus. The criteria are:

(a) All licensees infected with the Hepatitis B virus must successfully complete, no later than 6 months after receiving acknowledgment of their status from the Board, an educational program approved by the Board which will aid in a better understanding of the disease. In order to receive Board approval, the program must be at least 6 clock hours in duration and the program's curriculum must include, but is not limited to:

1. History and nomenclature of Hepatitis B virus;
2. Clinical relationship of Hepatitis B virus to other forms of viral hepatitis;
3. Hepatitis B virus mode of transmission and replication;
4. Blood curves in the clinical course of the Hepatitis B virus;
5. Clinical and laboratory characteristics of Hepatitis B virus infections;
6. The Hepatitis B virus infected licensee and his or her lifestyle;
7. The Hepatitis B virus infected licensee as a practicing health care professional;
8. Barrier techniques;
9. The consequences of a break in barrier techniques;
10. Proper mechanisms for reporting breaks in barrier techniques;
11. Sterilization and disinfection procedures in the operatory;
12. Sterilization and disinfection procedures in the laboratory;
13. Insurance and legal problems of Hepatitis B virus infected licensees; and
14. Hepatitis B virus vaccine.

Additionally, to obtain Board approval the program must also administer a written comprehensive examination covering each of the topics listed above which must be satisfactorily completed by a participant before the participant will be certified as having completed the program.

(b) Infected licensees will be monitored on a random basis at least once a year by Board approved consultants for the purpose of verifying compliance with sterilization, disinfection and barrier techniques. The monitors will verify compliance by utilizing the criteria set forth in Rule 64B5-25.005, F.A.C. The random monitoring will be performed in addition to any checks conducted by any county health department. The monitor's report shall be forwarded to the Board's Executive Director within 14 days of the monitor's visit.

(c) Infected licensees shall notify the patient, the Board's Executive Director and the local county health department at any time a barrier technique has been or may have been broken. The patient must be notified immediately. Telephonic notification must be accomplished within 24 hours and must be followed up by written notification no later than 72 hours after the barrier technique has been broken. Notification by the infected licensees shall include, at a minimum, the following information:

1. What barrier technique was broken;
2. Steps undertaken to notify affected patient; and
3. Steps undertaken to overcome the break in technique.

(3) A break in barrier technique includes but is not limited to any puncture, tear or cut in the gloves at any time during which contact with the patient is made or at any time a break, abrasion or cut of the skin occurs which could expose the patient to risk of infection.

(4) Each and every notice or report required pursuant to this rule or as a result of the application of this rule shall be confidential and exempt from the provisions of Section 119.07(1), F.S., as set forth in Section 466.041(3), F.S.

Specific Authority 456.032, 466.004(4) FS. Law Implemented 456.032, 466.028(1)(t), (v), (y), 466.041(3) FS. History—New 7-12-88, Amended 10-28-91, Formerly 21G-25.004, Amended 8-12-93, Formerly 61F5-25.004, 59Q-25.004.

64B5-25.005 Monitoring of Licensees Infected With the Hepatitis B Virus.

- (1) Licensees infected with the Hepatitis B virus will be monitored by Board approved consultants to verify compliance with accepted barrier techniques as set forth in Rule 64B5-25.004, F.A.C.
- (2) Board-approved consultants acting as monitors shall be required to successfully complete a Board approved educational program for licensees infected with the Hepatitis B virus as described in Rule 64B5-25.004, F.A.C., prior to monitoring any licensee infected with the Hepatitis B virus.
- (3) Monitors will perform their duties by making random, on-site visits at least once a year for a three (3) year period and at least tri-annually thereafter, to any clinical dental setting where an identified licensee infected with the Hepatitis B virus practices or is employed. The inspection and evaluation of compliance shall include the following procedures, the results of which must be reported to the Board's Executive Director within 14 days of the monitor's visit:
 - (a) Personal interviews with each member of the office staff regarding procedures which are followed in the clinical setting.
 - (b) Review of the dentist's appointment book to document the number of days the dentist has practiced since notification of being infected or the last evaluation, and the number of patients seen since that date.
 - (c) The number of boxes of examination and surgical protective gloves on hand and the number purchased since notification of infection or the last evaluation.
 - (d) The number and type of masks on hand and the number and type purchased since notification of infection or the last evaluation.
 - (e) A determination of whether all personnel since notification of infection or any new personnel since the last evaluation have been checked for surface antigens and surface antibodies and whether all personnel have been specifically educated regarding appropriate sterilization, disinfection and barrier technique necessary to prevent communication of the Hepatitis B virus.
 - (f) Identification and description of training provided and procedures and protocols utilized.
 - (g) A determination of whether all office personnel are familiar with procedures and reporting requirements which are necessary if a break in barrier techniques occurs.
 - (h) A determination of whether heat sterilization is routinely used and whether the heat sterilization is monitored monthly.
 - (i) A determination of the type of cold disinfectant used, its spectrum, brand name and chemical composition.
 - (j) A list of instruments and materials which are routinely cold sterilized and a determination of the efficacy of the procedures.
 - (k) Identification and documentation of any incidents of a break in barrier technique or potential breaks which were averted.
 - (l) Documentation of the monitor's conclusions regarding compliance which addresses the results of each of the procedures outlined above.
- (4) Should a monitor determine that unreported breaks in barrier techniques have occurred, or should the monitor determine that appropriate sterilization, disinfection and barrier techniques have not been followed adequately to protect the public, the monitor shall so notify the Board's Executive Director by telephone within 24 hours of the on-site inspection and provide written confirmation within 72 hours.

Specific Authority 456.032, 466.004(4), FS. Law Implemented 456.032, 466.028(1)(t), (v), (y), 466.041(3) FS. History—New 7-12-88, Amended 10-28-91, Formerly 21G-25.005, 61F5-25.005, Amended 10-16-96, Formerly 59Q-25.005.

64B5-25.006 Emergency Suspension of Licensees Infected With the Hepatitis B Virus; Initiation of Complaints.

- (1) Upon notification that any of the following events have occurred, the Board's Executive Director shall request an emergency Probable Cause Panel meeting. The panel shall determine whether the Secretary of the Department should be requested to institute an emergency suspension of the licensee infected with the Hepatitis B virus pursuant to Section 120.60(8), F.S.
 - (a) A monitor's report that the infected licensee has failed to report any break in barrier technique or that the infected licensee has failed to follow appropriate sterilization, disinfection and barrier techniques in a manner which adequately protects the public.
 - (b) Failure of the infected licensee to have successfully completed the Board approved educational program as required by Rule 64B5-25.004, F.A.C.

(c) A confirmed report that the infected licensee has failed to report a break in barrier technique as required by Rule 64B5-25.004, F.A.C.

(d) A confirmed report that a licensee is infected with the Hepatitis B virus and has failed to report his or her status to the Board as required by Rule 64B5-25.004, F.A.C.

(2) The Executive Director may consult with any monitor for technical assistance and may request confirmation of a report from the Office of Investigative Services prior to requesting an emergency Probable Cause Panel Meeting or initiation of a complaint.

(3) The Executive Director shall initiate a complaint or confirm that a complaint has already been initiated when a report of a break in barrier technique or a report of violation of Rule Chapter 64B5-25, F.A.C., is received. The Board does not intend this provision to discourage timely and accurate reporting or to imply that disciplinary action against a licensee will routinely be initiated by the Department. It is the Board's intent to protect the public and the licensee by assuring that an adequate investigation is made of any reported violation so that an informed decision can be reached regarding the safety of the licensee's continued practice.

Specific Authority 455.601, 466.004(4) FS. Law Implemented 455.601, 466.028(1)(t), (v), (y) FS. History—New 7-12-88, Amended 10-28-91, Formerly 21G-25.006, 61F5-25.006, 59Q-25.006.

64B5-25.007 Disposition of Biohazardous Waste.

(1) Licensees who generate biohazardous waste as defined by Chapter 64E-16, F.A.C., shall comply with the requirements of that chapter in order to maintain minimum sanitary conditions as required by Section 466.028(1)(v), F.S.

(2) Extracted teeth may be rendered non-biohazardous by disinfection so that they may be returned to the patient or the patient's legal guardian. Extracted teeth used for scientific, educational or testing purposes should first be cleaned of adherent patient material by scrubbing with detergent and water or by using an ultrasonic cleaner. Teeth should then be stored, immersed in a fresh solution of sodium hypochlorite (household bleach diluted 1:10 with tap water) or any liquid chemical germicide suitable for clinical specimen fixation.

(3) To render an extracted tooth non-biohazardous it must be decontaminated in accordance with the guidelines set forth in Rule 64B5-25.003, F.A.C.

(4) Extracted teeth and tissue fragments not required for microscopic examination shall be discarded as biohazardous waste or as a sharp in accordance with Chapter 64E-16, F.A.C.

Specific Authority 456.032, 466.004 FS. Law Implemented 456.032, 466.028(1)(v), 466.041 FS. History—New 11-16-89, Amended 1-7-92, Formerly 21G-25.007, Amended 3-30-94, Formerly 61F5-25.007, 59Q-25.007.

64B5-25.008 Shipment to Dental Laboratories.

Impressions, appliances and contaminated dental models sent to dental laboratories must be sealed in an impervious container and labeled "treat as infectious material" prior to shipment from a dental office.

Specific Authority 456.032, 466.004 FS. Law Implemented 456.032, 466.028(1)(v), (y), 466.041 FS. History—New 1-7-92, Formerly 21G-25.008, 61F5-25.008, 59Q-25.008.