

TRAIN FOR SUCCESS INC.  
Laws And Rules That Govern Dental Laboratories And Dental  
Technicians 3Hr

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## **PURPOSE**

The purpose of this course is to review the laws and rules that govern Dental Laboratories and Dental Technicians. The course reviews the Florida Statutes chapter 466 and the Florida Administrative Code 64B27-1 which includes the laws and rules concerning dental laboratory inspections, and practice, procedures for healthy and safe dental laboratory operation, information regarding dental laboratory biennial registration, continuing education requirements, registration certificates, change of ownership or address, violations, suspension, revocation and administrative fines.

## **OBJECTIVES/ GOALS:**

After successful completion of this course, the participants will be able to:

1. Discuss the laws and rules that govern Dental Laboratories and Dental Technicians,
2. Describe the laws concerning dental laboratory inspections,
3. Discuss the practice and procedure for healthy and safe dental laboratory operation,
4. Describe the procedures regarding dental laboratory biennial registration,
5. Discuss the requirement for continuing education,
6. Describe the laws and rules regarding change of ownership or address,
7. Discuss the laws and rules regarding violations, suspension, revocation and administrative fines.

# Dental laboratory

According to the Florida Statutes chapter 466.031, Dental laboratory is defined as used in this chapter, includes any firm, or corporation or person who performs for a fee of any kind, gratuitously, or otherwise, directly or through an agent or employee, by any means or method, or who in any way supplies or manufactures artificial substitutes for the natural teeth, or who furnishes, supplies, constructs, or reproduces or repairs any prosthetic denture, bridge, or appliance to be worn in the human mouth or who in any way holds itself out as a dental laboratory (F.S. 466.031)(1).

Excludes any dental laboratory technician who constructs or repairs dental prosthetic appliances in the office of a licensed dentist for such dentist only and under her or his supervision and work order (F.S. 466.031)(2).



# **Dental Laboratory Inspections, and Practice and Procedure for Healthy and Safe Dental Laboratory Operation**

According to the Florida Administrative code 64B27-1.001; regarding dental laboratory inspections, and practice and procedure for healthy and safe dental laboratory operation;

(1) Each dental laboratory that is registered by the Department of Health (DOH) to operate in the State of Florida shall be subject to periodic inspections by Department personnel at least one time during the calendar year. The inspections shall be conducted during the regular business hours and may take place with or without notice.

(2) The following practice and procedure shall be implemented by each registered dental laboratory in the State of Florida and be subject to inspection pursuant to subsection (1), of this section. Each registered dental laboratory shall:

(a) Be kept clean, in an orderly manner and in good repair, with regard to normal fabrication procedures at time of inspection,

(b) All waste materials must be disposed of properly at the end of each day according to local restrictions,

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According to the Florida Administrative code 64B27-1.001; regarding dental laboratory inspections, and practice and procedure for healthy and safe dental laboratory operation;

**A copy of the laboratory registration**

(c) A copy of the laboratory registration must be maintained on the laboratory premises, so it is readily available for inspection by the Department of Health personnel,

(d) Maintain on the laboratory premises for four years the original or electronic copy of a prescription from a licensed dentist for each separate appliance or artificial oral restorative oral device authorizing construction or repair of the specified artificial oral appliance and,

**Written policy & procedure regarding sanitation**

(e) A written policy and procedure document regarding sanitation must be maintained on the laboratory premises and the policy shall include, but not necessarily be limited to:

1. Intake and disinfection procedure for every appliance, impression, bite, or any other material that is posing a possible contamination risk received by the laboratory, and

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2. There should be a separate procedure for handling dental appliances, and impressions previously identified by the dentist, known to have come from carriers of the bloodborne pathogens; Hepatitis B Virus (HBV) and human immunodeficiency virus (HIV) virus.



According to the Department of Health (DOH), infection control procedures are designed to protect each individual, patients as well as employees of the Dental Laboratory. The infection control procedures will also help to prevent the cross contamination of the appliances.

Dental laboratory infection control procedure regarding the Hepatitis B Virus (HBV) and human immunodeficiency virus (HIV) includes;

- Exposure to possible infectious items; therefore all incoming cases should be handled and considered as if they were infectious.
- Before disinfecting any items, gloves have to be worn.

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- According to Occupational Safety and Health Administration (OSHA) standards, eye protection and mask are recommended.
- Never touch or handle any thing during the opening of a package and the disinfecting procedure until the entire procedure is completed. Then the gloves are removed and hand washing is completed using an anti-bacterial soap before beginning any other procedure.
- Each surface has to be cleaned and disinfected after each receiving session.
- Packages that contains material and merchandise should be opened prior to or after packages that contain prosthetics.
- The liquid disinfecting solutions may be disposed of into the sanitary sewer system.



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#### Dental laboratory sanitation control procedure

According to the Department of Health (DOH), sanitation control procedures are designed to protect each individual as well as each employee of the Dental Laboratory.

The Sanitation control procedures will also help to prevent the cross contamination of materials that are handled in the laboratory.

Regarding the sanitation control procedures:

- All employees are responsible for maintaining his/her work area, and the instruments, as well as any other materials that are used in his/her daily duties; then all needs to be cleaned, disinfected, and stored in the proper place.
- When the work day is finished, counter spaces need to be sprayed with a disinfecting solution and then wiped down.
- All trash has to be removed on a daily basis.
- All sinks has to be disinfected several times per day when they are being used for rinsing and steaming dental impressions and other types of dental work.
- Eating utensils should never be washed or stored with the dental laboratory work or supplies.
- Bathrooms has to be maintained, cleaned, and disinfected.
- The floors should be swept or vacuumed at the end of each day.
- The use of personal protective equipment (PPE): gloves, masks, and protective eyewear should be used as directed by the Occupational Safety and Health Administration (OSHA) OSHA whenever necessary.
- Dress code should be followed by the employees as directed by the employer.

According to the Department of Health (DOH) dental laboratory infection



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control procedure:

- Use a box cutter whenever necessary, open all the packages and store the box cutter.
- Put gloves on.
- Remove all packing material, carefully.
- Dispose of all packing materials.
- Individually identify the contents of every package and place on counter.
- Use the reference chart as a guide, spray, or dip the contents with the appropriate disinfecting solution.
- If blood or saliva is present or visible on the item, the item has to be rinsed thoroughly before spraying or dipping.
- After spraying or dipping, place the contents in plastic bag and seal.
- Place the bag and work order in the appropriate work pan. Work pan should not be placed on the receiving bench but on next work station.
- After all the packages have been opened, disinfected, and placed in work pans, spray the receiving counter with chorine solution until counter is completely covered with the solution. Use paper towel to wipe thoroughly and then discard the towels.
- Spray the counter again (2<sup>nd</sup> time) with light even cover and allow solution to dry.

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According to the Florida Administrative code 64B27-1.001; regarding dental laboratory inspections, and practice and procedure for healthy and safe dental laboratory operation; regarding

Designated receiving area

(3) Each registered dental laboratory shall have a designated receiving area. The following procedure shall be followed in the receiving area:

(a) Work surfaces and counter tops shall be constructed of non-porous materials which shall be disinfected daily with a chlorine compound, a combination synthetic phenolic, or an iodophor solution that has been diluted according to the manufacturer's directions.

(b) All the employees who are working in the receiving area will need to wear disposable gloves, and the employees, as an option they may wear a facial mask or protective eyewear.

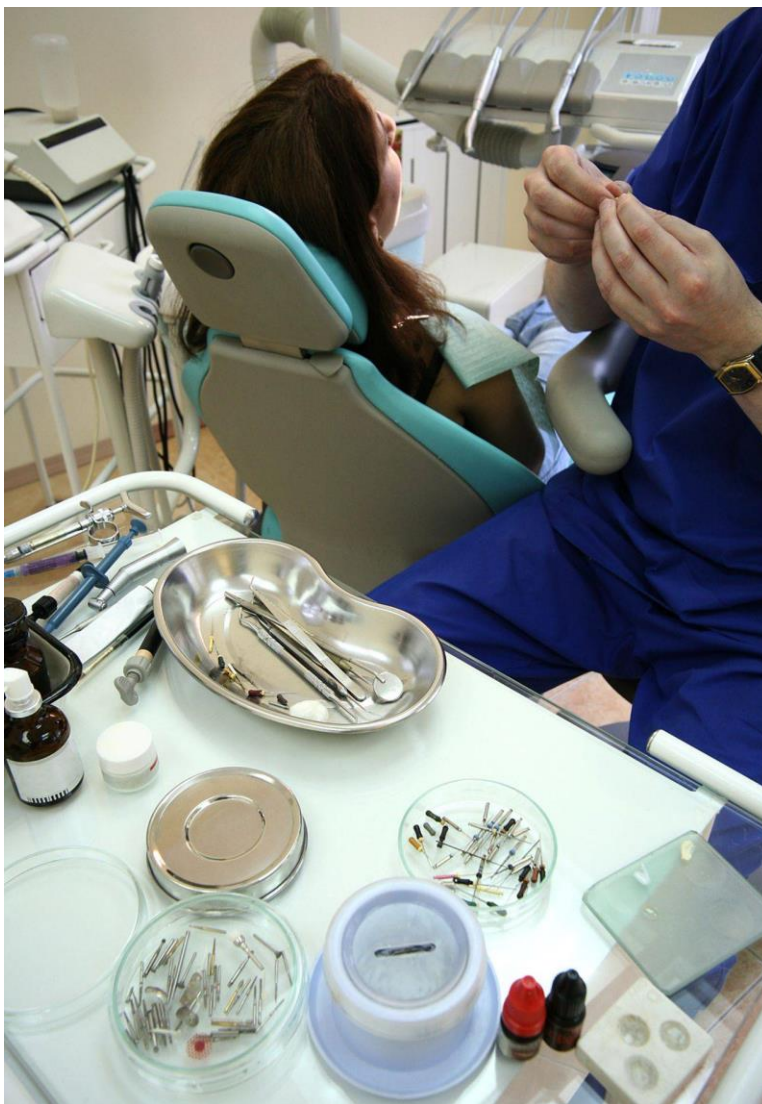
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*(4) The following dental equipment and supplies shall not be permitted in a registered dental laboratory in the state of Florida:*

*(a) Dental chairs.*

*(b) X-ray machines.*

*(c) Anesthetics, sedatives, or medicinal drugs, other than personal prescriptions (F.A.C. 64B27-1.001).*



# Dental Laboratory Biennial Registration

According to Florida Administrative Code (F.A.C.) 64B27-1.002, regarding Dental Laboratory Biennial Registration,

The Department of Health (DOH) shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of 2 years, after the Department has received from the registering person, firm, or corporation:

(1) The registration form DH-MQA 1228 (7/17 ), Dental Laboratory Registration Application, incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=ref-#####>.

## [VIEW CHANGES](#)

The person that can be contacted regarding the proposed rule is: Jennifer Wenhold, The Executive Director, 4052 Bald Cypress Way, Bin #C-08, Tallahassee, Florida 32399 or [Jennifer.Wenhold@FlHealth.gov](mailto:Jennifer.Wenhold@FlHealth.gov).

(2) A biennial registration fee of \$200.00; and

(3) The operator of a dental laboratory shall notify the Department of a change in ownership or address within 30 days. The closure of the laboratory constitutes a change of address. Failure to timely notify the Department of a change in ownership or address, including closure of a laboratory, is grounds to deny an application for registration of a laboratory.

# Continuing Education Requirements



According to Florida Administrative Code 64B27-1.003 regarding Continuing Education Requirements;

1. On or after July 1, 2010, each registered dental laboratory owner/operator or a designated employee must complete 18 hours of continuing education (CE) biennially.

The owner/operator or agent as listed on the registration has the responsibility to ensure that the CE provider has submitted, or the owner has self-submitted course completion information within the CE tracking system in accordance with rule Chapter 64B-5, F.A.C.

The records retained by the laboratory to document completion of the required CE shall either include evidence that the owner/operator completed the course hours or that the course hours were completed by a designated employee who worked at the laboratory for at least one full year during the

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biennium as documented by time cards, pay stubs, or federal W-2 forms.

2. Various organizations, schools, and other agencies that meet the criteria set in Section 466.032, F.S., and in this rule shall apply and will be granted approval to develop and offer continuing education courses in accordance with Rule 64B5-12.017, F.A.C.

3. As part of the hours that are required biennially, the owner/operator or designated employee must complete 2 hours of coursework relating to the prevention of medical errors including root-cause analysis, error reduction and prevention, including patient safety, infection control, and/or standards on employee safety required by federal or state laws or regulations (F.A.C. 64B27-1.003).

According to Florida Administrative Code 64B27-1.003 regarding Continuing Education Requirements;

(4) As part of the Continuing Education hours that are required biennially, the owner/operator or designated employee needs to complete a 1 to 3 hour course on the laws and rules that govern the dental laboratories and the dental technicians.

(5) Attendance at conventions, lectures, college courses, study clubs, and research shall be included for fulfillment of the Continuing Education (CE) requirement if sponsored for dentists or dental technicians by an approved provider or if approved by the executive director for dental laboratories and the Board of Dentistry as meeting the content requirements specified by law (F.A.C. 64B27-1.003).

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### Approved providers

For an up-to-date report on approved providers contact the office regulating dental laboratories at 4052 Bald Cypress Way, Bin #C08, Tallahassee, Florida 32399, telephone number (850)245-4474.

According to Florida Administrative Code 64B27-1.003 regarding Continuing Education Requirements;

(6) Designated employees or owners that are certified by the National Board for Certification in Dental Laboratory Technology as a Dental Laboratory Technician during the biennium is able to demonstrate compliance with the continuing education requirements of this rule by entering his or her Certified Dental Technician certification number and submitting a copy of his or her active certification card in the CE tracking system (F.A.C.64B27-1.003)(6).

(7) As part of the hours that are required biennially, the owner/operator or designated employee may satisfy up to 4 hours by the performance of pro bono services to the indigent or the underserved populations who are in areas of critical need provided that the prescribing dentist is serving these populations and the patient beneficiary falls within one of these categories (F.A.C.64B27-1.003)(7).

(8) The CE requirement does not apply to a dental laboratory physically located within the office of a licensed dentist (F.A.C.64B27-1.003)(8).

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**Continuing Education (CE) Requirements for FLORIDA**

<b>REQUIRED SUBJECT AREA</b>	<b>REQUIRED NUMBER OF HOURS</b>	<b>ADDITIONAL INFORMATION</b>
General Hours	13 to 15 Hours	The total general hours will depend on the number of hours completed in the Laws and Rules that govern dental laboratories and dental technicians course
Medical Error	2 Hours	Must be Board Approved
Laws and Rules	1 to 3 Hours	Course can be a minimum of 1 hour or up to 3 hours. Coursework must be based on laws and rules that govern dental laboratories and dental technicians.



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According to the 2017 Florida Statutes, chapter 466.021; retention of dental laboratories by dentist; penalty:

Each licensed dentist who uses the services of any dental laboratory for the purpose of altering, constructing, repairing, or duplicating any denture, implant, partial denture, veneer, bridge splint, orthodontic or other prosthetic appliance, or other suitable form of artificial oral restorative device will be required to furnish the dental laboratory with a written prescription that is in a form prescribed by rule of the board (F.S. 466.021).

The prescription shall be dated and signed by the dentist and shall include the license number of the dentist, the patient's name or number with sufficient descriptive information that will clearly identify each separate and individual piece of work to be performed by the dental laboratory, and a specification of materials to be contained in each work product (F.S. 466.021).

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According to the 2017 Florida Statutes, chapter 466.021; retention of dental laboratories by dentist; penalty:

A copy of the prescription shall be retained in a file in the prescribing dentist's office for a period of 4 years following the date the prescription was issued, and the original prescription shall be retained in a file by the dental laboratory for a period of 4 years (F.S. 466.021).

A registered dental laboratory shall disclose in writing at the time of delivery of the final restoration to the prescribing dentist the materials and all certificates of authenticity that constitute each product manufactured and the point of origin of manufacture of each restoration, including the address and contact information of the dental laboratory (F.S. 466.021).

The file of prescriptions to be kept by the dentist and the dental laboratory shall be open to inspection at any reasonable time by the department or its constituted agent. Failure of the dentist to keep records of each prescription shall subject the dentist to suspension or revocation of her or his license to practice dentistry in this state (F.S. 466.021).

Failure of a dental laboratory that has accepted a prescription to have the original or electronic copy of each prescription and to ensure the accuracy of each product's material disclosure at the time it is delivered to the prescribing dentist as required by this section is admissible evidence of a violation of this chapter and constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

This section does not preclude a registered dental laboratory from working for another registered dental laboratory if that work is performed pursuant to written authorization, in a form to be prescribed by rule of the board, which evidences that the originating laboratory has obtained a valid prescription and which sets forth the work to be performed and the resulting material certifications to be provided (F.S. 466.021).

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According to the 2017 Florida Statutes, chapter 466.021; retention of dental laboratories by dentist; penalty:

A dental laboratory accepting prescriptions from dentists is liable for damages caused by inaccuracies in the material disclosure, certificates of authenticity, or point of origin provided by the dental laboratory to the prescribing dentist.

This section does not preclude a registered laboratory from providing its services to dentists licensed and practicing in another state if that work is requested or otherwise authorized in written form that clearly identifies the name and address of the requesting dentist and sets forth the work to be performed and otherwise complies with all applicable laws and treaties (F.S. 466.021).



# Registration

According to the Florida Statutes Chapter 466.032, regarding Registration:

(1) Each person, corporation or firm that is operating a dental laboratory in the state of Florida, shall register biennially with the department on forms to be provided by the department and, at the same time, pay to the department a registration fee not to exceed \$300 for which the department shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of 2 years (F.S. 466.032).

(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4) (F.S. 466.032).

(3) Any dental laboratory operator who has not complied with subsection (1) within 3 months after the registration renewal date shall be required to pay a delinquency fee of \$40 in addition to the regular registration fee (F.S. 466.032).

(4) The department is authorized to commence and maintain proceedings to enjoin the operator of any dental laboratory who has not complied with this section from operating a dental laboratory in this state until she or he has obtained a registration certificate and paid the required fees (F.S. 466.032).

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(5) A dental laboratory owner or at least one employee of any dental laboratory renewing registration on or after July 1, 2010, shall complete 18 hours of continuing education biennially. Programs of continuing education must be programs of learning that contribute directly to the education of the dental technician and may include, but are not limited to, attendance at lectures, study clubs, college courses, or scientific sessions of conventions and research (F.S. 466.032).

(a) The aim of continuing education for dental technicians is to improve dental health care delivery to the public as such is impacted through the design, manufacture, and use of artificial human oral prosthetics and related restorative appliances (F.S. 466.032).

(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Laboratory and technological subjects, including, but not limited to, laboratory techniques and procedures, materials, and equipment; and
2. Subjects pertinent to oral health, infection control, and safety.

(c) Programs that meet the general requirements of continuing education may be developed and offered to dental technicians by the Florida Dental Laboratory Association and the Florida Dental Association. Other organizations, schools, or agencies may also be approved to develop and offer continuing education in accordance with specific criteria established by the department.

(d)1. This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.

2. A dental laboratory in another state or country which provides service to a dentist licensed under this chapter is not required to register with the state and may continue to provide services to such dentist with a proper prescription. However, a dental laboratory in another state or country may voluntarily comply with this subsection.

## Registration certificates

According to Florida Statutes chapter 466.033 regarding registration certificates:

The department shall not require an examination, but shall issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by the department under s. 466.038 (F.S. 466.033).

# Change of ownership or address



## Change of ownership or address

According to Florida Statutes chapter 466.034 regarding change of ownership or address; when the ownership or address of any dental laboratory operating in the state of Florida is changed, the owner thereof shall notify the department within 30 days of such change of ownership or address.

# Advertising

According to Florida Statutes chapter 466.035 regarding advertising;

Dental laboratories ***shall not*** advertise or solicit directly or indirectly, by card, mail, pamphlet, newspaper, television, radio, or otherwise to the general public to construct, reproduce, or repair prosthetic dentures, bridges, plates, or other appliances to be used or worn as substitutes for natural teeth or for the regulation of natural teeth (F.S.466.035).





# Information, periodic inspections, equipment and supplies

According to Florida Statutes chapter 466.036 regarding information, periodic inspections, equipment and supplies;

the Department of Health (DOH) may require from the applicant for a registration certificate to operate a dental laboratory any information necessary to carry out the purpose of this chapter, including proof that the applicant has the equipment and supplies necessary to operate as determined by rule of the department, and shall require periodic inspection of all dental laboratories operating in the state of Florida (F.S. 466.036).



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According to Florida Statutes chapter 466.036 regarding information, periodic inspections, equipment and supplies;

Such inspections shall include, but not be limited to,

- Inspection of sanitary conditions, equipment, supplies, and facilities on the premises.

The department of Health shall specify dental equipment and supplies that **are not permitted** in a registered dental laboratory (F.S. 466.036).



# **Suspension and Revocation; Administrative fine**

According to Florida Statutes chapter 466.037 regarding suspension and revocation; administrative fine:

The department of Health (DOH) may suspend or revoke the certificate of any dental laboratory registered under s. 466.032, for failing to comply with the provisions of this chapter or rules adopted by the department of Health under this chapter. The department of Health may impose an administrative fine.



# Rules

According to Florida Statutes chapter 466.038 regarding Rules;

The department, upon consultation with the Board of Dentistry and industry representatives of the dental laboratory profession, has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to enforce the provisions of this chapter pertaining to and regulating dental laboratories.

# Violations

## Misdemeanor of The Second Degree

According to Florida Statutes chapter 466.039 regarding violations;

It shall be unlawful for any firm, or corporation or person to operate as a dental laboratory as defined in this chapter, except those registered as provided in s. 466.032. Violation shall constitute a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

# RESOURCES

**For more information; click on links below:**

## **Florida Statutes**

- [Section 466.021:](#) Retention of dental laboratories by dentist; penalty
- [Section 466.031:](#) “Dental Laboratory” defined
- [Section 466.032:](#) Registration
- [Section 466.033:](#) Registration certificates
- [Section 466.034:](#) Change of ownership or address
- [Section 466.035:](#) Advertising
- [Section 466.036:](#) Information; periodic inspections; equipment and supplies
- [Section 466.037:](#) Suspension and revocation; administrative fine
- [Section 466.038:](#) Rules
- [Section 466.039:](#) Violations

## **Florida Administrative Code**

- [Rule 64B27-1.001:](#) Dental Laboratory Inspections, and Practice and Procedure for Healthy and Safe Dental Laboratory Operation
- [Rule 64B27-1.002:](#) Dental Laboratory Biennial Registration
- [Rule 64B27-1.003:](#) Continuing Education Requirements
- [Rule 64B27-2.001:](#) Disciplinary Guidelines
- [Rule 64B27-2.002:](#) Notice of Noncompliance for Minor Violations
- [Rule 64B27-2.003:](#) Citation Authority
- [Rule 64B27-2.004:](#) Mediation

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