[DOH ADMINISTRATIVE ORDER NO. 2008-0010, May 07, 2008]

REVISED RULES AND REGULATIONS GOVERNING THE REGISTRATION AND LICENSURE OF DENTAL LABORATORIES IN THE PHILIPPINES

I. Rationale

FOURmula ONE for Health is the implementation framework for reforms in the Philippines. The main objective of the regulatory reforms is to assure access to quality and affordable products, devices, facilities and services, especially those most commonly use by the poor.

The Department of Health in constitutionally mandated to protect and preserved the health of the people including oral health, In support to its mandate, Presidential Decree No. 1542. "Providing for the Registration and Licensing of Dental Prosthetic Laboratories" was issued on June 11, 1978. To implement this decree, the DOH formulated the rules and regulations. With the current advances in dentistry, the services of dental prosthetic laboratories expanded. Consistent with Executive Order No. 102 dated May 24, 1999, "Redirecting the Functions and Operations of the Department of Health", the latest revision of the rules and regulations was embodied in Administrative Order No. 28 s. 2003 and Administrative Order No. 105 s. 2003, both known as "Revised Rules and Regulations Governing the Registration, Licensure of Dental Laboratories in the Philippines". After 5 years of implementation, the Bureau of Health Facilities and Services, the main instrumentality of the DOH responsible for setting and reviewing regulatory policies and standards of health facilities, is amending A.O. No. 28, s 2003 and A.O. No. 105, s. 2003.

II. Objective

These rules and regulations are promulgated in order to a) strengthen the regulatory policy that will protect the public health and at the same time ensure the safety and welfare of the community, b) ensure high compliance among stakeholders and c) consider advances in technology of dental laboratories.

III. Scope

These rules and regulations shall apply to any person, firm, corporation or entity, whether government or private, operating and maintaining dental laboratories.

However, the following are not covered by these rules and regulations a) dental labo- ratories in schools solely for teaching and training, b) those solely for manufacturing integral parts or accessories in denture making.

IV. Definition of Terms

For purposes of this rules and regulations, the following definitions are provided:

- A. BHFS refers to the Bureau of Health Facilities and Services, the licensing and regulatory arm of the DOH.
- B. CHD- refers to the Center for Health Development, the regional office of the DOH. C DOH C. DOH- refers to the Department of Health.
- D. LTO- refers to the License to Operate, a formal authorization issued by the DOH to an individual, corporation, association or organization to operate a dental laboratory.
- E. PRC refers to the Professional Regulation Commission.
- F. Dentist a person who is a holder of valid certificate of registration and professional identification card in Destistry, and who renders dental service within the meaning and intent of R.A. No. 9484, known as " The Philippine Dental Act of 2007", and its Rules and Regulations.
- G. Dental Technologist a person who is a holder of valid certificate of registration and professional identification card, and who renders technical services within the meaning and intent of R.A. No. 9484, known as "The Philippine Dental Act of 2007", and its Rules and Regulations.
- H. Laboratory Technician a person who renders technical services in a dental laboratory under the supervision of a dental technologist.
- I. Technical Services the design and fabrication of oral/dental appliances prescribed by the dentist to be installed in the patient's mouth and surrounding tissues, repair of previ ously fabricated oral/dental appliances, and consultation services to the dentist for treatment planning.
- J. Dental Laboratory an establishment engaged in making, preparing, providing, or altering oral/dental appliances which are prescribed by the dentist, given back to the dentist, and installed to the patient's mouth. It includes services performed in a dental prosthetic laboratory.
- K. Dental Technician a person, either a dental technologist or a laboratory technician, who performs the various services in a dental laboratory.
- L. Appliances artificial devices used to influence the shape of the jaws, bring the teeth and jaws into proper alignment, restore natural teeth, or replace missing teeth and cranio-facial tissues.
- M. Dentures artificial substitutes for missing teeth and adjacent tissues.
- N. Orthodontics diagnosis and treatment of malocclusions (improper bites) by use of corrective appliances (i.e., braces, retainers, headgears)-
- O. Prosthodontics rehabilitation of oral function and esthetic by the restoration of natural teeth and/or replacement of missing teeth and craniofacial tissues with

artificial substitutes (i.e. complete dentures, crowns, implant retained/supported appliances).

V. Guidelines

A. General Guidelines.

- 1. A license shall be issued to a dental laboratory that meets the standards and technical requirements as set forth in these rules and regulations.
- 2. An inspection tool, which prescribes the standards and technical requirements for the issuance of LTO, shall be formulated by BHFS. It shall be posted in the DOH website (http://www.doh.gov.ph).
- 3. A licensed dentist engaged in making, preparing, providing, or altering oral/ dental appliances solely for his/her practice shall be exempted from securing LTO. However, a licensed dentist providing dental laboratory services to other dentists or advertising a dental laboratory through signage or publication shall be required to secure LTO.

B. Specific Guidelines

- 1. classification of Dental Laboratories.
 - 1.1 Ownership
- 1.1.1 Private privately owned, established and operated with fund through donations, principal, investment or other means, by any individual, corporation, association or organization.
- 1.1.2 Government operated and maintained partially or wholly by a national, provincial, city, municipal or other political unit; or by any department, division, board or agency thereof.
- 1.2 Service Capability
- 1.2.1 Removable Prostheses Services fabrication and repair of dental pros-theses that can be taken out of the mouth and put back by the patient. Any of, but not limited to, the following services is provided:
 - 1.2.1.1 Complete dentures
 - 1.2.1.2 Overdentures
 - 1.2.1.3 Orthodontic appliances
 - 1.2.1.4 Temporo-mandibular joint appliances
 - 1.2.1.5 Removable partial dentures

1.2.1.5.1. Without metal framework

1.2.1.5.1.1	conventional	acrylic
dentures		
1.2.1.5.1.2	Thermoplastic/flexible	
dentures		

- 1.2.1.5.2 With metal framework
- 1.2.1.5.3 With metal framework (without casting)
- 1.2.1.6 Special removable appliances
 - 1.2.1.6.1 Maxillo-facial prostheses
 - 1.2.1.6.2 Implant-retained removable appliances
- 1.2.1.7 Special removable appliances (without casting)
 - 1.2.1.7.1 Maxillo-facial prostheses
 - 1.2.1.7.2 Implant-retained removable appliances
- 1.2.2. Fixed Prostheses Services-fabrication and repair of dental prostheses that are cemented to a natural or artificial tooth. Any of, but not limited to, the, following services is provided:
 - 1.2.2.1 Crown and Bridge
 - 1.2.2.1.1 Without metal alloy substructure metalfree crowns and bridges with ceramics, composites or resins
 - 1.2.2.1.2 With metal alloy substructure ceramics or resins fused to metal, or purely metal alloy
 - 1.2.2.1.3 With metal alloy substructure-ceramics or resins fused to metal, or purely metal alloy (without casting)
 - 1.2.2.2 Special Fixed Prostheses
 - 1.2.2.2.1 Dental attachments
 - 1.2.2.2.2 Implant-retained fixed prostheses
 - 1.2.2.3 Special Fixed Prostheses (without casting)
 - 1.2.2.3.1 Dental attachments
 - 1.2.2.3.2 Implant-retained fixed prostheses
- 1.2.3 Removable and Fixed Prostheses Services fabrication and repair of both removal and fixed dental prostheses. A combination of any of the abovementioned services is provided.
- 1.2.4 Limited Services fabrication and repair of a specific component of dental prostheses. Only one of the following services is provided:
 - 1.2.4.1 Casting and framework soldering
- 2. Standards for a Dental Laboratory
- 2.1 Human Resources
- 2.1.1 A dentist or a dental technologist shall supervise the dental

laboratory and ensure that it complies with the standards and technical requirements as set forth in these rules and regulations at all times,

2.1.2 There shall be an adequate number of dental technician, either a den tal technologist or a laboratory technician, and support personnel to perform the various services in the dental laboratory.

2.2 Equipment/Instruments

- 2.2.1 There shall be available and functional equipment/instruments for efficient, safe and hygienic operation of the dental laboratory.
- 2.2.2 There shall be written and observed procedure for proper maintenance of equipment/instruments.

2.3 Physical Plant

- 2.3.1 There shall be functional areas, based on services provided, that are clean, safe, well lighted and well ventilated.
 - 2.3.1.1 Areas shall be reasonably free from smoke, dust and foul odor.
 - 2.3.1.2 Areas shall be reasonably free from hazards to the life and safety of personnel and the public.
 - 2.3.1.3 Areas shall be provided with sufficient illumination and airflow.
- 2.3.2 There shall be designated and separate areas for metal casting and ceramic processing.
- 2.3.3 There shall be smooth and orderly flow of people and supplies.
- 2.3.4 The dental laboratory shall be segregated and strictly for its activities.
- 2.3.5 It shall observe as moke-free environment
- 2.3.6 No pets shall be allowed with the premises of the dental laboratory.
- 2.3.7 There shall be written and observed procedure for proper maintenance of physical plant.

2.4 Records

2.4.1 The dental laboratory shall maintain records of work instructions that legible, stored and readily retrievable in a suitable environment to prevent damage, deterioration and loss.

2.5 personnel Safety

2.5.1 Appropriate safety devices such as casting gloves, safety goggles laboratory gown, face mask, dust evacuator or its equivalent, shall be