PREFACE to the NADL GUIDELINES FOR ESTABLISHING STATUTORY REGULATIONS OF DENTAL LABORATORIES

This NADL regulatory guideline was designed to be a minimum standard of regulation – a type of state legislation that would be beneficial for the general public and effective for both the dental and dental laboratory professions.

The members and leaders of a state dental laboratory association must explore crucial areas and make difficult decisions and commitments prior to seeking any regulation at the state level. They must be certain that their crusade for regulation is in the best interest of the public health and welfare and that it is not self-serving. They must then convince their state legislature that this is so! First and foremost, the industry and profession within a particular state should be behind such an effort and therefore, due diligence through surveying laboratories and/or technicians in a given state should take place prior to moving forward with a particular proposal to ensure collective support, interest and commitment.

State Legislators feel strongly that the protection of the health and safety of the public is the foundation upon which all state dental practice acts and other healthcare regulatory legislation should be based. They also feel that the public welfare should be protected with a minimum amount of governmental interference in this free enterprise system.

Before legislators agree to license or adopt certification standards for persons in any occupation, they are likely to explore other less stringent regulatory approaches. Among the alternatives to individual licensing is the enforcement or strengthening of existing statutes relating to deceptive or unfair trade practices. Another is the assignment of inspection or other supervisory authority to an existing agency: e.g., a department of health or department of licensing and registration. A third alternative is to license or register establishments rather than individuals.

TYPES OF REGULATION

REGISTRATION

Registration is an appropriate form of regulation when the threat to life, health, safety and economic well-being is relatively small and when other forms of legal redress are available to the public. In its simplest form, registration requires that an individual file his or her name and address on behalf of himself or herself for or on behalf of an entity (the dental laboratory) with a designated agency. There is usually no pre-entry screening by a regulatory board. Registration in this form does little more than provide a roster of practitioners or facilities/businesses.
CERTIFICATION

Certification is a form of regulation which grants recognition to individuals who have met predetermined qualifications established by a state agency or other recognized body. Only those who meet the qualifications and maintain their certification may legally use the designated title. However, non-certified individuals may offer similar services to the public as long as they do not describe themselves as being “Certified.” Certification is especially appropriate when the public needs assistance in identifying competent practitioners but where the risk to health and safety may not be severe enough to warrant full licensure of individuals working in a particular occupation.

Either of the above could be coupled with minimum standards set by the state agency such as requirements on storage of prescriptions, health and safety/infection control standards, etc.

LICENSURE

Individual licensing is a process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency through education, testing, certification or a combination of each required to ensure that the public health, safety and welfare will be reasonably well protected. Legislators would have to be convinced that this protection is absolutely necessary in order to have an individual licensing bill passed.

LABORATORY REGULATION

Governing Agency

Regulation of a dental laboratory addresses the establishment of standards for the business entity rather than for the individual technician.

The NADL regulatory guideline endorses registration of the dental laboratory facility in conjunction with registration of at least one Certified Dental Technician in the laboratory upon whom each credential depends.

NADL feels strongly that the important issue is the passage of regulation based on education and experience requirements, not the agency under which such regulation is accomplished.

The important issue is the passage of legislation that is based on education and experience requirements at least equal to those established by the National Board for Certification in Dental Laboratory Technology (NBC).

Several possible governing bodies include, but are not limited to, the following examples:

1. Board of Dental Laboratory Examiners
2. Department of Health
3. Professional Regulatory Board
4. State Board of Dentistry

Requirements for Regulation

Regulation of the dental laboratory facility, as addressed in this guideline, follows the standards established by the National Board for Certification in Dental Laboratory Technology for Certified Dental Laboratories (CDL). These standards set forth minimum requirements for health, safety, infection control procedures, facility equipment and conditions. Certified Dental Laboratories must also employ Certified Dental Technicians in supervisory positions in each certified specialty department.

Registration of dental technicians follows standards established by the National Board for Certification in Dental Laboratory Technology (NBC), which examines and credentials technicians in each of five specialties. State regulations may require additional education and experience; the Certified Dental Technician (CDT) requirement is considered, for the purposes of this Model Bill, to be the minimum requirement for registration.

1. Certified Dental Technician
   The certification program administered by the National Board for Certification in Dental Laboratory Technology represents the only education and experience standards established for dental technology. In order to be regulated, a dental laboratory should be required to employ at least one Certified Dental Technician or the equivalent. It is the only dental technician certifying body recognized by the American Dental Association and it is accredited by the American National Standards Institute.

2. OSHA Compliance/Infection Control
   The National Board for Certification in Dental Laboratory Technology requires that certified laboratories install and practice effective infection control procedures. These should be a minimum requirement for a regulated dental laboratory.

3. Grandfather Clause/Grace Period for Compliance
   If there is a demonstrated need for regulation of dental laboratories to protect the public health and welfare, it follows that all laboratories in existence when a regulatory bill is passed should be required to comply with the standards and regulations of the bill within a reasonable period of time.

4. Disclosure
   There should be adequate disclosure of material content and point of origin of the manufacture of each restoration delivered to the dentist.

5. In Office Dental Laboratories
   Dental laboratories that are physically located in a dental office would be exempt from compliance of the model bill as the licensed practitioner, the dentist is on site to oversee process, but best practices would encourage voluntary compliance.
MODEL BILL FOR DENTAL LABORATORIES AND DENTAL TECHNICIANS

Originally Adopted June 1988
Amended June 1992
Amended December 2005

Whereas, this Legislature [General Assembly] finds that the health, safety and welfare of the citizens of this State [Commonwealth] are promoted by the establishment of the regulatory procedures for the dental laboratory industry, it is hereby resolved that the following shall be enacted:

SECTION I. Purposes:
The purpose of this Act is to promote the health, safety and welfare of the citizens of this State [Commonwealth] by requiring dental laboratories conducting business in this state employ at least one Certified Dental Technician certified by the National Board for Certification in Dental Laboratory Technology be permitted to engage in the manufacture and repair of dental prosthetic appliances as hereinafter provided.

SECTION II. Definitions:

2.1 Dental Laboratory: A commercial dental laboratory is a corporation, partnership or sole-proprietor engaged in the manufacture or repair of dental prosthetic appliances on the prescription of and for a licensed dentist or the work authorization of another commercial dental laboratory; provided, however, that the provisions of this paragraph are subject to the exemptions contained in Section VI of this Act.

2.2 Dental Technician:
Shall mean any person who offers or undertakes to perform or accomplish dental technology.

2.3 Certified Dental Technician:
Shall mean a dental technician who has met the standards set by the National Board for Certification in Dental Laboratory Technology or its equivalent as established by this state.

2.4 Licensed Dentist:
Shall mean any person duly licensed to practice dentistry under any statutes of this State [Commonwealth] or practitioners licensed in other states.

2.5 Prescription:
Shall mean a written instrument executed by a licensed dentist and directed to a regulated dental laboratory authorizing the manufacture or repair of a dental prosthetic appliance for such licensed dentist.

2.6 Work Authorization:
Shall mean a written instrument executed by a regulated dental laboratory authorized by prescription by which such dental laboratory subcontracts all or part of
the fabrication or repair of a dental prosthetic appliance authorized by prescription to another regulated dental laboratory.

**SECTION III. REGULATION**

3.1 Upon the effective date of this Act, all dental laboratories operating, doing business or intending to operate or do business within this State [Commonwealth] shall be required to register with the department. In order to be regulated under this Act, a dental laboratory must employ or be operated under the supervision of one or more Certified Dental Technicians as defined in this Act.

3.2 In order to be regulated under this Act, a dental laboratory shall practice infectious disease control as required by OSHA.

3.3 A dental laboratory wherever located shall be considered as operating or doing business in this State [Commonwealth] if its work product is prepared pursuant to a written instrument originating within this State [Commonwealth].

3.4 A dental laboratory shall disclose to the dentist the material content of a prescribed restoration with any contraindications for purposes of ensuring the health and safety of the patient.

3.5 A dental laboratory shall disclose to the dentist the point of origin and location(s) of manufacture of the prescribed restoration.

**SECTION IV. PENALTIES FOR USE OF NON-REGULATED DENTAL LABORATORY**

4.1 It shall be illegal for any dentist licensed in this State to have a dental prosthetic appliance manufactured in a dental laboratory, in the State or otherwise that does not meet the regulatory requirements of this State.

**SECTION V. IN OFFICE DENTAL LABORATORIES**

5.1 Dental laboratories physically located within a dental office shall be exempt from all sections except 3.2 of this law.

**SECTION VI. EFFECTIVE DATE**

This Act shall become effective after becoming law.

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