

CUSTOM-MADE DENTAL PROSTHESES AND APPLIANCES

1 Introduction

- 1.1 Australian dental laboratories are regulated to a limited degree by the business constraints of Federal, State and Local Government legislation. These regulations address occupational health and safety, infection control, quality of materials used and waste management.
- 1.2 Some Australian dental laboratories and dentists source custom-made dental prostheses and appliances from overseas. The constraints that apply to Australian dental laboratories may not apply to overseas laboratories.
- 1.3 For many years, Australian Governments have supported free-trade agreements and universal application of competition policy.
- 1.4 The Therapeutic Goods Administration (TGA) regulates the standards of dental materials, instruments and equipment, mostly recognising standards of the International Organisation for Standardisation. (ISO).
- 1.5 **Definitions**
 - 1.5.1 CUSTOM-MADE DENTAL PROSTHESIS OR APPLIANCE is any prosthesis or appliance made for a particular patient either directly in the mouth by a dental care provider or indirectly from an impression of the mouth.
 - 1.5.2 DENTAL CARE PROVIDER is a person registered by a board to provide dental care.

2 Principles

- 2.1 The health and safety of patients is paramount.
- 2.2 The fitting and intra-oral adjustment of dental prostheses and appliances is part of the practice of dentistry.

3 Policy

- 3.1 Dentists and dental prosthetists have a responsibility to be aware that all materials used in custom-made dental prostheses and appliances should comply with Therapeutics Goods (Medical Devices) Regulations 2002 and its amendments (TGR 2002).
- 3.2 Dental laboratories and suppliers of custom-made dental prostheses and appliances have a responsibility to ensure and guarantee that laboratory work complies with TGR 2002.
- 3.3 The origin of all dental prostheses and appliances should be identified.
- 3.4 All materials used in custom-made dental prostheses and appliances, wherever sourced, must comply with ISO standards.

Policy Statement 5.17

Adopted by ADA Federal Council, April 10/11, 2008.
Amended by ADA Federal Council, April 16/17, 2009.