College of Chiropodists of Ontario

PRACTICE STANDARD

Safety and the Manufacturing and Modification of Orthotic Devices

Reviewed and Updated: January 29, 2026

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Part I: Definitions

Manufacturing Orthotics:

Manufacturing orthotics involves creating custom medical devices that support, correct, or alleviate musculoskeletal or neuromuscular issues, primarily in the feet, ankles, and lower limbs. These devices, also known as orthoses, can be designed to address a wide range of conditions, from foot deformities and gait abnormalities to injuries and pain.

Modifying Orthotics:

Modifying orthotics involves the use of materials to adjust or change a pre-existing orthotic device to further meet the needs of the patient.

Part II: Manufacturing Orthotic Devices

Registrants must develop and maintain safe orthotic device manufacturing practices and must ensure that procedures are in place to keep registrants, patients and staff safe.

1. The procedures for orthotic device manufacturing and the manufacturing site (room or lab) itself must comply with the following legislation or guidelines:
    1. Occupational Health and Safety Act and Regulations for Industrial Establishments (R.R.O. 1990, Reg. 851: INDUSTRIAL ESTABLISHMENTS).
    2. Workplace Hazardous Materials Information System (WHMIS regulation).
    3. Workers Compensation Act
    4. Ontario Fire Code
    5. Ventilation for Acceptable Indoor Air Quality[1]
    6. Canadian Electrical Code
    7. Regulation made under the Occupational Health and Safety Act for Health Care and Residential Facilities.
    8. Canadian Standards Association [2]
    9. American National Standard for Emergency Eyewash and Shower Protection[3]

[1] American Society of Heating, Refrigerating, Air Conditioning Engineers, Inc. (ASHRAE) 62 – 1989, 1791 Tullie Circle NE, Atlanta, Ga., 30329-2305 Phone 404-636-8400, FAX 404-321-5478
[2] Canadian Standards Association, Z316.5 Fumehoods and Exhaust Systems. (This document is available in draft form only at this time and is expected to be published by December 1993)
[3] In the absence of a Canadian standard, the ANSI Z358.1, 1981 is used.

2. Registrants must maintain the orthotic device manufacturing site/lab with a door, separate and away from the patient treatment room.

3. Registrants must manufacture orthotic devices under the following controlled conditions:

A. General ventilation

- The orthotic device lab or site must be adequately supplied with intake air to replace the air taken away by the exhaust.

B. Local ventilation

- All gluing, heating and drying of orthotic materials must be carried out by the registrant within a fumehood[4] that has a capture velocity of no less than 500 cubic ft/min. (**Note:** a "range" type hood is not acceptable.)
- The contaminated air should be drawn away from the registrant and not through the registrant's breathing zone.
- If grinding is performed, a fume hood which has a capture velocity of no less than 1200 cubic feet/min is recommended. The fume hood should have a filter to capture the dust.

C. Personal protective equipment

- Registrants must wear a National Institute for Occupational Safety and Health (NIOSH) approved personal respirator when manufacturing orthotics, grinding or gluing orthotic materials and when mixing plaster. (Note: a respirator is optional if a fume hood is used as described above).
- Registrants must wear NIOSH approved goggles when grinding orthotic materials.
- Registrants must wear protective clothing that is not worn for the treatment of patients. For example, a lab coat or apron.
- Registrants must wear rubber gloves when handling adhesives, thinners and plaster.

D. Handling orthotic materials

- Registrants must have a material safety data sheet (MSDS) and must comply with all sections for all materials used in the manufacturing of orthotics.
- All orthotic device manufacturing sites must have a facility for the registrant to wash their hands and face after the fabrication of orthoses.
- Registrants must review and revise handling instructions for all orthotic materials annually. MSDS are to be kept in the registrant's WHIMIS binder
- Registrants must store a minimal amount of hazardous material on site.
- Flammable materials must be stored separately from other orthotic materials in an approved flammable storage cabinet.

E. Emergency equipment

- All orthotic device manufacturing sites must have the appropriate extinguishing media for all orthotic materials used, as required by the Ontario Fire Code (see MSDS for each material used in orthotic device lab.)
- All orthotic device manufacturing sites must have an eyewash station (see section 1, IX).
- All orthotic device manufacturing sites must have a first aid kit.

[4] A fume hood is defined by CSA as follows:
"An enclosed space ventilated by an induced flow through the face opening intended to capture and contain vapours, dusts, mists and fumes generated within the enclosure. These airborne contaminants are then exhausted from the cabinet and either filtered or exhausted to a remote location. The fumehood consists of a side, top and back enclosure, panels, a work surface and face opening."

Part III: Modifying Orthotic Devices

1. The procedures for orthotic device modification and the modification site (room or lab) must be compliant with the following legislation or guidelines:
    1. Occupational Health and Safety Act and Regulations for Industrial Establishments (R.R.O. 1990, Reg. 851: INDUSTRIAL ESTABLISHMENTS).
    2. Workplace Hazardous Materials Information System (WHMIS regulation).
    3. Workers Compensation Act
    4. Ontario Fire Code
    5. Ventilation for Acceptable Indoor Air Quality[5]
    6. Canadian Electrical Code
    7. Regulation made under the Occupational Health and Safety Act for Health Care and Residential Facilities.
    8. Canadian Standards Association [6]
    9. American National Standard for Emergency Eyewash and Shower Protection [7]

2. Registrants must maintain the orthotic device manufacturing site/lab with a door, separate and away from the patient treatment room when using modification materials that could pose risk to the patient, such as glues and adhesive materials.

3. Registrants must manufacture orthotic devices under the following controlled conditions:

    A. General ventilation
    - The orthotic device lab or site must be adequately supplied with intake air to replace the air taken away by the exhaust in cases where modifications using glues or adhesives are performed.

    B. Local ventilation
    - All gluing of orthotic materials shall be carried out by the registrant in an adequately ventilated room.
    - The contaminated air should be drawn away from the registrant and not through the registrant's breathing zone.
    - If grinding is performed, a vacuum device must adequately filter and capture the dust.

[5] American Society of Heating, Refrigerating, Air Conditioning Engineers, Inc. (ASHRAE) 62 – 1989, 1791 Tullie Circle NE, Atlanta, Ga., 30329-2305 Phone 404-636-8400, FAX 404-321-5478
[6] Canadian Standards Association, Z316.5 Fumehoods and Exhaust Systems. (This document is available in draft form only at this time and is expected to be published by December 1993)
[7] In the absence of a Canadian standard the ANSI Z358.1, 1981 is used.

C. Personal protective equipment

- Registrants wear a National Institute for Occupational Safety and Health (NIOSH) approved personal respirator when grinding or gluing orthotic materials. (Note: a respirator is optional if a fume hood is used as described above).
- Registrants must wear NIOSH approved goggles when grinding orthotic materials.
- Rubber gloves must be worn by registrants when handling adhesives, thinners and plaster.

D. Handling orthotic materials

- Registrants must have a material safety data sheet (MSDS) and must comply with all sections for all materials used in the modification of orthotics.
- All orthotic device manufacturing sites must have a facility for the registrant to wash their hands and face after modifying orthoses.
- Registrants must review and revise handling instructions for all orthotic materials annually. MSDS are to be kept in the registrant's WHIMIS binder
- Registrants must store a minimal amount of hazardous material on site.
- Flammable materials must be stored separately from other orthotic materials in an approved flammable storage cabinet.

E. Emergency equipment

- All orthotic device manufacturing sites must have the appropriate extinguishing media for all orthotic materials used, as required by the Ontario Fire Code (see MSDS for each material used in orthotic device lab.)
- All orthotic device manufacturing sites must have an eyewash station (see section 1, IX).
- All orthotic device manufacturing sites must have a first aid kit.