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**Compulsory  
Ethiopian Standard**

**Second Edition  
2020**

**Dental laboratory Requirement**



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## Foreword

This Ethiopian Standard has been prepared under the direction of the Technical Committee for Health service. (TC 198) and published by the Ethiopian Standards Agency (ESA).

This Compulsory Ethiopian Standard cancels and replaces ES 3611:2012.

This Compulsory Ethiopian Standard cancels and replaces ES 186:2001.

Application of this standard is COMPULSORY with respect to clauses 4.1,4.8,4.9 and 5.0. A Compulsory Ethiopian Standard shall have the same meaning, interpretation and application of a "Technical Regulation"as implied in the WTO-TBT Agreement.

Implementation of this standard shall be effective as of 01 October 2013.

## Dental Specialty Clinic Requirement

### 1. Scope

These Ethiopian standards provide minimum requirements for the establishment and maintenance of dental laboratory with respect to practices, premises, professionals and products or materials put into use for the clinic.

### 2. Normative References

### 3. Terminologies and Definitions

**3.1. Appropriate Organ:** Shall mean a state government organ authorized to implement food, medicine and healthcare administration and control activities at a state level;

**3.2. Authority:** Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

**3.3. Proclamation:** Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control proclamation No 661/2009.

**3.4. Appropriate Law:** Shall mean a law issued by a state to implement regulatory activities regarding food, medicine and healthcare.

**3.5. Person:** Shall mean any physical or juridical person.

**3.6. Authorized Person:** Shall mean any specialty clinic staff who is responsible for a given service.

**3.7. Dental laboratory:** Shall mean a dental work room that is operated as a part of a dental office or stand alone engaged in, constructing, repairing, or altering prosthetic dentures, bridges, orthodontic or other appliances, or structures to be used as substitutes for or as a part of human teeth or jaws or associated structures, or for the correction of malocclusions or deformities.

#### 4. General Requirement

- 4.1 The dental laboratory shall be directed by licensed dental technician.
- 4.2 The dental laboratory shall have a program of continuous quality improvement for the service which includes regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.
- 4.3 The dental laboratory shall establish quality team to improve quality of service deliveries.
- 4.4 The dental laboratory shall assess its staffs current knowledge and practice and observes utilization of national guidelines for the services it renders every six month.
- 4.5 The dental laboratory shall provide or facilitate training to their staffs.
- 4.6 The dental laboratory shall display the following at visible place:
  - a) List of Services available in the clinic during working hours & after working hours,
  - b) List of Professionals working in the clinic during & after working hours,
  - c) Updated list of Various fees and prices,
- 4.7 The dental laboratory facilities shall be well marked and easily accessible for persons with disability.
- 4.8 The dental laboratory shall have fire extinguisher placed in visible area.
- 4.9 All employees, including part-time and contract shall be trained in fire-fighting equipment and patient evacuation of clinic's buildings as part of their initial orientation and at least annually thereafter.
- 4.10 Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labelled with the date of the last inspection.
- 4.11 Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.
- 4.12 All rooms shall be provided with running water supply & functional hand washing basin.
- 4.13 The Internal surfaces of the clinic (floors, walls, and ceilings) shall be:
  - a. Smooth, impervious, free from cracks, **recesses, and projecting ledges.**
  - b. Easy to clean and decontaminate effectively,
  - c. Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics.

- 4.14 The circulation ways and sub corridors shall be a minimum 1.60m wide.
- 4.15 Patient serving corridors should not be less than 2.40m wide.
- 4.16 Glass doors shall be marked to avoid accidental collision.
- 4.17 Dental laboratory where functional units are at different floor shall have a mechanism of accessing all the functioning rooms horizontally either by stairs and ramp or stair and elevator.
- 4.18 The dental laboratory shall carryout workload analysis.

## 5. Specific Requirement

### 5.1 Outpatient Services

#### 5.1.1 Practices:

- 5.1.1.1 The Dental laboratory shall be functional at least during working hours.
- 5.1.1.2 All services rendered in dental laboratory shall be in accordance with request/ prescription issued by authorized dental personnel (DDM/ DDS/ BDS/ Dental Therapist).
- 5.1.1.3 Dental lab shall have protocols & SOPs for services rendered in the lab.
- 5.1.1.4 Dental laboratory shall give or produce the following preparations:
  - a. Negative impression and positive dental cast,
  - b. Dental models, artificial denture and plate,
  - c. In lay and on lay
- 5.1.1.5 The dental laboratory shall have records for client dental models.
- 5.1.1.6 All activities performed in the dental lab shall comply with the national infection prevention guidelines.
- 5.1.1.7 Any procedures related to dental extraction and treatment are strictly prohibited at dental laboratory level.

#### 5.1.2 Premises

- 5.1.2.1 The facility for Dental laboratory shall have the following premises:

Premises required	# required	Minimum Area required
Reception, recording area and patient waiting room	1	9sq. m
Dental Laboratory room	1	12sq. m
Store room with shelves	1	9sq. m
Toilet room	1	4 sq. m

- 5.1.2.2 All rooms shall have adequate light, water and ventilation

**5.1.3 Professionals**

5.1.3.1 The Dental laboratory shall be directed by a licensed Dental technician.

5.1.3.2 The dental clinic shall have the following minimum number of staff:

<b>Professional required</b>	<b>Number required</b>
Dental technician	1
Assistance /Cleaner	1

**5.1.4 Products**

5.1.4.1 The dental laboratory shall have the following equipment and instruments:

a. Prosthodontics Instruments (ex. Impression tray)

b. Basic Dental Laboratory Equipments:

- Model trimmer Vibrator
- Bench lathe
- Vacuum Spatulator
- Bench motor with Hand piece
- Casting unit
- Arch articulator
- Set up & units for heating & processing dentures materials
- Laboratory Knife
- Coping saw
- Laboratory spatula
- Different pans used for disinfections & sterilization of instruments
- Boiler or Dry heat oven
- Porcelain carvers
- Acrylic stones
- Stones for gold alloy
- Bunsen burne

5.1.4.2 The clinic shall have the following supplies and equipment needed for infection prevention and control practice.

a. Waste management equipment and supplies:

- Incinerator (mobile) with Ash pit
- Garbage bins
- Plastic garbage bags (optional)
- Safety boxes

b. Cleaning appliances

c. Laundry appliances

- Sink
- Washing basin
- Drying rack/line
- Irons

d. Personal Protective Equipment

- Heavy duty glove
- Surgical glove
- Surgical mask

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## **5.2 Housekeeping & Maintenance Services**

### **5.2.1 Practices**

5.2.1.1 The housekeeping service shall have the following activities.

- a. Basic cleaning such as dusting, sweeping, polishing and washing
- b. Special cleaning of
  - Different types of floors
  - Wall & ceiling
  - Doors & windows
  - Furniture & fixtures
  - Venetian blinds
- c. Cleaning and maintenance of toilet.
- d. Water treatment, filtering & purification.

5.2.1.2 Maintain an adequate supply of clean white coat and gowns at all times.

5.2.1.3 In the housekeeping service, the types and sources of offensive odors shall be identified, controlled and removed immediately

5.2.1.4 Collection, transportation and disposal of specialty clinic wastes shall be supervised and controlled

5.2.1.5 The safety of fire, electrical and natural hazards in the risk areas in the specialty clinic shall be supervised and controlled and shall work closely with specialty clinic fire brigade and safety committee.

5.2.1.6 The designee shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the specialty clinic.

5.2.1.7 The housekeeping staffs shall create pleasant environment to patients, staffs and visitors

5.2.1.8 The housekeeping staffs shall ensure proper lighting and ventilation in different specialty clinic areas.

5.2.1.9 Regular surveillance of overhead and underground tank, proper cover, regular chlorination and cleaning shall be undertaken

5.2.1.10 The infection control measures shall be carried out in accordance with the specialty clinic infection prevention standard

5.2.1.11 There shall be reserve electrical generator for power supply for continuous 24 hours.

5.2.1.12 Potable water and electrical services shall be available 24 hours a day and 365 days a year through regular or alternate sources.

5.2.1.13 There shall be a plant safety maintenance organization as described below:

- a. A safety committee that develops a comprehensive clinic-wide safety program and reviewed.
- b. A mechanism to report all incidents, injuries and safety hazards to the safety committee.
- c. The safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.

5.2.1.14 Facility maintenance services

- a. The building maintenance service shall have written policies and procedures that are reviewed for routine maintenance, preventive maintenance and renovation maintenance.
- b. The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.
- c. Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.
- d. Routine inspections of elevators shall be conducted.

5.2.1.15 Construction and renovation

- a. Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.
- b. The infection control program shall review areas of potential risk and populations at risk.

5.2.1.16 There shall be written protocols and procedures for specialty clinic equipment maintenance including:

- a. Plan for equipment maintenance (both preventive and curative), replacements, upgrades, and new equipments
- b. Safe disposal procedures
- c. An effective tracking system to monitor equipment maintenance activity.
- d. A monitoring method that ensures diagnostic equipment operates with predicted specificity and sensitivity.

5.2.1.17 The maintenance personnel including the management of the clinic shall take basic trainings on the following issues and this shall be documented.

- a. Building fabrics and utilities
- b. Building services and economics

- c. Planning maintenance demand
- d. Preventive and routine maintenance practice
- e. Maintenance with regard to IP and hygiene

5.2.1.18 Fire and emergency preparedness

- a. The clinic shall comply with the National Fire Protection standard
- b. All employees, including part-time employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and evacuation from the building as part of their initial orientation and shall receive printed instructions on procedures and at least annually thereafter.
- c. A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall.
- d. Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labeled with the date of the last inspection.
- e. Fire detectors, alarm systems, and fire suppression systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last **two** inspections shall be kept on file.
- f. There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.

5.2.1.19 Housekeeping equipment or supplies used for cleaning in contaminated areas shall not be used in any other area of the clinic before it has been properly cleaned and sterilized.

5.2.1.20 All areas of the clinic, including the building and grounds, shall be kept clean and orderly.

5.2.1.21 There shall be frequent cleaning of floors, walls, woodwork and windows.

5.2.1.22 The premises shall be kept free of rodent and insect infestations.

5.2.1.23 Accumulated waste material and rubbish shall be removed at frequent intervals.

5.2.1.24 No flammable cleaning agents or other flammable liquids or gases shall be stored in any janitor's closet or other area of the clinic except in a properly fire rated and properly ventilated storage area specifically designed for such storage.

5.2.1.25 If the clinic does not have its own housekeeping and maintenance services; it may have a contract agreement with external organizations.

5.2.1.26 If the clinic has given the housekeeping and maintenance services to a contractor, the contractual agreement shall be filed and made accessible in the clinic premises. In such cases the clinic shall

make sure that the standards mentioned for housekeeping and maintenance are adhered by the contractor.

## **5.2.2 Premises**

5.2.2.1 There shall be separate space provided for the storage of housekeeping equipment and supplies

5.2.2.2 Office shall be available for the maintenance and the housekeeper.

5.2.2.3 Adequate space shall be available for janitor's closets and cleaning equipment & supplies.

5.2.2.4 Exits, stairways, doors and corridors shall be kept free of obstructions.

5.2.2.5 The clinic shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough fuel to maintain power for at least 24 hours.

## **5.2.3 Professionals**

5.2.3.1 The housekeeping and maintenance personnel shall take basic trainings on the following issues and this shall be documented in their personal profile.

- a. Basic principles of sanitation and peculiarity to clinic environment.
- b. Basic principles of personal hygiene
- c. Basic knowledge about different detergent and disinfectants
- d. Basic knowledge about cleaning equipments operation techniques and their maintenance.
- e. Different processes of water treatment & purification, removing bacteria.
- f. Basic principles of ventilation, composition of air, air flow, humidity and temperature.
- g. Common types of odors and their sources of origin, identification and control.
- h. Removal and control technique of different types of odors.
- i. Various equipments and materials used for odor control operation.
- j. Medical waste, source and generation of waste
- k. Hazards of medical waste to population and community.
- l. Principles of collection of different types of medical wastes
- m. Operational procedures of equipments
- n. Safety measures in operation
- o. Clinic lay out, configuration work, flow of men, material and equipment in different areas. Air, water, noise, pollution, causes of pollution and their control and prevention.

5.2.3.2 In summary, if the service is not outsourced, the clinic shall have

- a. Designated personnel for housekeeping,

- b. General maintenance personnel (electrician, plumber, painter, building maintenance technician and
- c. Biomedical equipment maintenance technician.

#### **5.2.4 Products**

5.2.4.1 The clinic shall have the following tools, equipment & materials for housekeeping services.

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- a. Reserve electrical generator
- b. Floor wiping brush
- c. Ceiling brush
- d. Glass cleaning / wiping brush.
- e. Dustbins paddles
- f. Plastic Bucket
- g. Gum boots
- h. Heavy duty glove
- i. Gown, Masks
- j. Cleaning material
- k. Deodorants & disinfectant
- l. Insecticides & rodenticides

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## Bibliography

The latest editions of the following laws, regulations, directives and guidelines shall be taken as part and parcel of this Ethiopian Standard.

1. Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009
2. Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No. 189/2010
3. National Health Policy of the Transitional Government of Ethiopia, 1993
4. National Drug Policy of the Transitional Government of Ethiopia, November 1993
5. Commercial Code of Ethiopia
6. Criminal Code of Ethiopia
7. Medicines Waste Management and Disposal Directive No 2/2011
8. Ethiopian National Guideline for Health Waste Management, 2008
  
9. Ethiopian Building Proclamation, No. 624/2009