

Guideline for Establishment of Other Services



**Health Intervention and Technology Assessment Division
Department of Health Services
Ministry of Health**

Version history

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1 Introduction

The Ministry of Health (MoH) is mandated under the Healthcare Services Rules and Regulations (HSRR) 2025 to regulate healthcare-related services in order to safeguard public health, safety, and well-being. Category IX: other services comprises establishments that do not primarily provide clinical care but deliver services that may pose risks related to hygiene, sanitation, infection prevention, and occupational health if not properly managed.

These services include, but are not limited to, massage centres, tattoo and body piercing studios, beauty parlours, and similar premises where close physical contact, use of shared equipment, or skin-penetrating procedures may occur. Inadequate controls in such settings can result in the transmission of infections or other health hazards affecting clients, workers, and the wider community.

This guideline has been developed to provide clear and consistent guidance to proponents seeking authorisation to establish or operate Category IX services. It outlines the minimum documentation and system requirements necessary to demonstrate compliance with regulatory expectations, including infrastructure adequacy, infection prevention and control (IPC) measures, waste management, workforce competency, and occupational health and safety.

The requirements set out in this guideline are applied using a risk-based approach. Proponents are expected to submit documentation proportionate to the nature, scale, and risk profile of the services proposed. Compliance with this guideline is a prerequisite for authorisation and supports effective regulatory oversight, standardisation of practices, and continuous improvement in service quality and public health protection.

2 Scope

This guideline specifies the minimum documentation and system requirements for the authorisation, renewal, variation, and regulatory oversight of healthcare-related centres classified under Category IX: Other Services, as defined by the HSRR 2025.

This guideline applies to establishments that provide non-clinical services which may pose risks to health, safety, hygiene, sanitation, infection prevention, or occupational health, including but not limited to:

- a) massage and body therapy centres;
- b) tattooing and body piercing studios;
- c) beauty parlours, and cosmetic service centres; and
- d) other similar services as may be determined by the MoH.

This guideline does not replace or supersede any applicable laws, regulations, standards, or requirements. Where inconsistencies arise, the provisions of the HSRR 2025 and other applicable legislation shall prevail.

The MoH may apply additional or more stringent requirements based on risk assessment, nature of services, or public health considerations.

3 Objectives

The objectives of this guideline are to:

- a) establish clear, consistent, and proportionate documentation requirements for the authorisation of centres classified under Category IX: other services;
- b) ensure that such centres are planned, established, and operated in a manner that safeguards public health, client safety, and worker safety;
- c) promote effective hygiene, sanitation, IPC, and waste management practices appropriate to the nature and risk profile of the services provided;
- d) support risk-based regulatory decision-making by enabling the MoH to assess organisational capacity, infrastructure readiness, and operational controls prior to authorisation;
- e) encourage the adoption of systematic management practices, including defined roles, procedures, and records, consistent with recognised quality management principles;
- f) facilitate continuous improvement in service quality, safety, and regulatory compliance through ongoing monitoring, inspection, and oversight; and
- g) provide a structured and predictable authorisation pathway that balances public health protection with ease of compliance for service providers.

4 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Healthcare Services Rules and Regulations (HSRR) 2025.

National guideline on infection control and medical waste management, Ministry of Health, Bhutan.

Regulation on Occupational Health, Safety and Welfare, 2022.

WHO guidelines on hand hygiene in health care, 2009.

Relevant national standards, technical guidelines, or circulars issued by the MoH or other authorities relating to hygiene, sanitation, IPC, and public safety.

5 Terms and definitions

For the purposes of this guideline, the following terms and definitions apply.

5.1 Authorisation

Formal approval granted by the MoH permitting the establishment and operation of a Category IX: other services centre, subject to compliance with applicable laws, regulations, and conditions.

5.2 Category IX: other services

Healthcare-related services not classified under other healthcare centre categories, which may pose hygiene, sanitation, or infection prevention risks, including but not limited to massage centres, tattoo and body piercing studios, beauty parlours, and similar establishments.

5.3 Centre

A physical establishment or premises from which Category IX services are provided to clients.

5.4 Environmental cleaning and disinfection

Systematic processes for cleaning and disinfecting surfaces, equipment, and environments to reduce microbial contamination.

5.5 Hand hygiene facility

A designated facility equipped with running water, soap or hand cleansing agents, and hygienic means of hand drying, intended for effective hand hygiene by staff and clients.

5.6 Higher-risk services

Category IX services that involve invasive procedures, exposure to blood or body fluids, or increased likelihood of infection or injury.

5.7 High-level disinfection

A validated disinfection process that inactivates or eliminates all microorganisms, including vegetative bacteria, mycobacteria, fungi and viruses, except for small numbers of bacterial spores, and that is applied to instruments or surfaces when sterilisation is not feasible or practical; this process shall be performed following thorough pre-cleaning and in accordance with the manufacturer's instructions.

5.8 Infection prevention and control

Evidence-based practices, procedures and measures that are designed to prevent or reduce the transmission of infectious agents during service delivery, including the identification of risks, implementation of protective actions and consistent application of standard precautions and other appropriate controls to protect clients, workers and the environment from avoidable infection.

5.9 Invasive procedure

Any procedure that is intended to puncture, cut, compromise or otherwise break the skin or mucous membrane, including but not limited to tattooing, body piercing, micro-pigmentation and similar practices where an instrument, needle or device penetrates the body surface.

5.10 Occupational health and safety

All measures, systems and practices that are established to protect the health, safety and welfare of workers by preventing work-related injuries, illnesses and hazards through risk assessment, control of workplace hazards, training, safe work procedures and health monitoring, and to ensure safe and healthy conditions for people in the workplace.

5.11 Proponent

An individual, partnership, company, or legal entity that applies for authorisation to establish or operate a Category IX centre.

5.12 Risk-based approach

A systematic approach to regulation in which the identification, assessment and prioritisation of health and safety hazards and their associated likelihood and severity of harm shall inform the determination of regulatory requirements, control measures and enforcement actions, such that the depth, stringency and frequency of regulatory intervention shall be proportionate to the level of risk posed, with higher-risk activities requiring more stringent controls and lower-risk activities subjected to an appropriately reduced regulatory burden.

5.13 Sharps

Objects or instruments with sharp points, edges or protuberances that are capable of cutting, puncturing or penetrating the skin or mucous membranes, including but not limited to needles, lancets, scalpels, blades and similar devices, whether contaminated or uncontaminated.

5.14 Single-use disposable item

An item that is intended by the manufacturer to be used once on a single client or for a single procedure and then discarded, and that is not designed or validated to be reprocessed for reuse.

5.15 Sterilisation

A validated process that destroys or eliminates all forms of microbial life, including bacterial spores, on instruments or equipment so that they are free of viable microorganisms. This process may be achieved by physical or chemical means and is intended to render the item sterile.

5.16 Waste management plan

A documented system that describes the organised processes for waste generated during service delivery, including the segregation, handling, storage, transport,

treatment and disposal of waste in a manner that protects health, prevents exposure to hazards, and complies with applicable safety and environmental requirements.

6 Acronyms

For the purposes of this guideline, the following acronyms apply:

CID	citizenship identity card
IPC	infection prevention and control
ISO	international organization for standardization
MoH	Ministry of Health
OHS	Occupational health and safety
QMS	quality management system
SOP	standard operating procedure

7 Administrative and legal documentation

- 7.1 The proponent shall submit a completed application form in the format prescribed in annexure I.
- 7.2 The application form shall be signed by the proponent or their authorised representative.
- 7.3 The proponent shall submit proof of legal identity, which shall include one of the following, as applicable:
 - a) copy of citizenship identity card (CID) for individual proprietors; or
 - b) certificate of incorporation or business registration for corporate entities.
- 7.4 Where the proponent is a company or partnership, governance documentation shall be provided, including:
 - a) ownership details; and
 - b) authorisation or board resolution nominating a responsible person in charge.

8 Premises and location

- 8.1 The proponent shall provide the full address and a location map of the proposed premises.
- 8.2 Where required, local authority or municipal clearance shall be submitted.

9 Business and operational plan

- 9.1 The proponent shall submit a documented business and operational plan describing the proposed establishment and its operations in sufficient detail to demonstrate feasibility, intent and preparedness for service delivery.
- 9.2 The business and operational plan shall, at a minimum, include:
 - a) a description and scope of services to be provided, clearly identifying the types of services and any special service features;
 - b) a justification of need for the services at the proposed location, supported by relevant market, demographic or community data;
 - c) an organisational structure and management responsibilities section, indicating governance, staffing roles and responsibilities and reporting relationships; and
 - d) estimated hours of operation and expected client volume, including weekly or daily service hours and projected service throughput.

9.3 The business plan shall be proportionate to the scale and complexity of the proposed services and shall demonstrate that resources, staffing, and operational processes are adequate to deliver the services safely and effectively.

10 Infrastructure and layout documentation

- 10.1 The proponent shall submit infrastructure and layout documentation for the proposed premises in a schematic form that accurately represents the physical and functional organisation of the centre.
- 10.2 The documentation shall include the following elements:
 - a) a schematic floor plan of the premises, drawn to scale, showing the name and function of each room or space, with clear labelling of functions and circulation paths for both clients and staff;
 - b) the floor area of each room or space, expressed in square metres or equivalent units, and an indication of internal clearances and access arrangements;
 - c) client and staff movement flow, illustrating logical circulation that supports safe, efficient service delivery and minimises cross-contamination or operational conflicts during normal operations;
 - d) a schedule of accommodation listing the type, number, location and size of rooms, spaces and support areas required for the proposed services;
 - e) documentation of utilities essential for hygiene and safety, including but not limited to:
 - 1) water supply, drainage and wastewater systems;
 - 2) ventilation and lighting provisions necessary for adequate air exchange, comfort, hygiene and safe operational conditions;
 - 3) hand hygiene facilities and locations of handwashing stations and dispensers; and
 - 4) toilet and sanitation facilities for clients and staff, appropriately sited and accessible.
 - f) The submitted plans and documents shall reflect actual site conditions, conform to applicable building, safety and public health codes, and be sufficient to enable verification during the licensing process.

11 Infection prevention and control

- 11.1 The proponent shall establish, maintain and submit documented IPC procedures that are evidence-based, facility-specific and consistent with the National guideline on infection control and medical waste management.

11.2 The IPC documentation shall include, at a minimum, documented procedures for:

- hand hygiene procedures, specifying methods, indications, agents and points of care where hand hygiene shall be performed in accordance with recognised IPC principles;
- environmental cleaning and disinfection methods, describing the scope, frequency, responsible persons, agents and validation of cleaning and disinfection activities to prevent environmental contamination;
- linen and reusable material management, detailing the segregation, handling, transport, cleaning, and storage of linen and reusable materials to prevent cross-contamination; and
- instrument and equipment decontamination processes, including pre-cleaning, cleaning, disinfection or sterilisation, criteria for method selection, staff responsibilities and record keeping.

11.3 Where the proposed services involve skin penetration, invasive procedures or potential exposure to blood or body fluids, the IPC documentation shall also include documented procedures for:

- sterilisation or high-level disinfection methods, specifying validated methods, quality controls, monitoring and verification consistent with the level of microbial risk; and
- use of single-use disposable items, including criteria for use, disposal and tracking to ensure items intended for one-time use are not reprocessed or reused.

12 Waste management

12.1 The proponent shall establish, maintain and submit a documented waste management plan that is appropriate to the nature and volume of waste generated by the services provided and that demonstrably protects health, safety and the environment.

12.2 The waste management plan shall address, at a minimum:

- segregation of waste, including classification at the point of generation into appropriate waste streams, such as general, infectious and sharps, and the use of distinct, labelled and colour-coded containers or receptacles for each category to prevent cross-contamination and facilitate safe handling;
- handling and disposal of sharps, where applicable, including the provision of puncture-proof sharps containers at point of use, safe storage until disposal, and methods to eliminate injury risk and potential infectious hazard; and

- c) arrangements with waste disposal service providers, specifying how waste streams not managed on-site will be collected, transported and treated or disposed of.

13 Human resource documentation

- 13.1 The proponent shall establish, maintain and submit human resource documentation that demonstrates the qualifications, roles, responsibilities and competence of all personnel involved in the delivery of the proposed services.
- 13.2 The documentation shall include, at a minimum:
 - a) a list of all personnel, clearly indicating their roles and responsibilities within the service delivery context;
 - b) evidence of relevant qualifications, skills or training for personnel performing services, including copies of certificates, degrees, licences, professional registrations or equivalent documentation that demonstrate competency; and
 - c) records of training in infection prevention and control, occupational safety and hygiene practices, and other applicable service-specific safety topics, maintained in a manner that is readily available for inspection.

14 Equipment and materials

- 14.1 The proponent shall establish, maintain and submit documented information on equipment and materials required to support safe and effective service delivery.
- 14.2 The documentation shall include, at a minimum:
 - a) an inventory of major equipment and tools used in service delivery, including identification details, such as description, make/model, location, manufacturer/supplier, and any relevant operational or maintenance status;
 - b) documentation of consumables used on clients, including details of the type and intended use, source of supply, and shelf-life information, where applicable;
 - c) material safety data sheets (MSDS) or safety data sheets (SDS) for all chemicals and substances that pose health or safety risks, maintained and made readily accessible to relevant personnel to support safe handling, storage, use and emergency response in accordance with applicable hazard communication practices.

15 Occupational health and safety

- 15.1 The proponent shall establish, maintain and submit a documented workplace health and safety plan that is appropriate to the nature, scale and risk profile of

the services provided and that ensures the protection of workers, clients and other persons present on the premises.

15.2 The plan shall include, at a minimum, documented procedures for:

- a) fire safety and emergency evacuation procedures, including methods for reporting fires and other emergencies, identification of escape routes and assembly points, roles and responsibilities during an emergency, and procedures to ensure safe and orderly evacuation of all persons from the premises;
- b) availability and maintenance of first aid facilities, including the provision of first aid equipment, designated first aid responders where required, and accessibility of first aid resources consistent with the risks present in the workplace; and
- c) incident and injury reporting mechanisms, specifying how work-related incidents, injuries, near misses and hazards shall be reported, recorded and investigated, including responsibilities, timelines and corrective action processes that prevent recurrence.

16 Declarations and undertakings

16.1 The proponent shall submit a signed declaration by the authorised representative confirming the following:

- a) compliance with applicable laws and regulations – that the proponent and its proposed services shall comply with all applicable national laws, regulations, standards and regulatory requirements applicable to establishment, operation and safety;
- b) accuracy and completeness of submitted information — that all information, documents and representations submitted in support of the application are true, accurate, complete and not misleading to the best of the proponent's knowledge, and that the proponent shall notify the MoH of any changes or corrections as soon as they arise; and
- c) consent to inspection, monitoring and regulatory oversight — that the proponent consents to inspections, audits, monitoring and regulatory oversight by the MoH for the purposes of verifying compliance with authorisation conditions, standards and applicable laws, and shall permit access to premises, records and personnel as necessary.

17 Risk-based additional documentation

17.1 Where the proposed services are assessed by the MoH as higher risk, the proponent shall provide additional documented information that supports safe, ethical and accountable service delivery. Such risk-based documentation shall include, but not be limited to, the following:

- a) Client consent forms, outlining the specific risks, benefits and alternatives of procedures that involve elevated risk, and ensuring informed consent has been obtained prior to service delivery; this documentation shall identify the client, the procedure(s) for which consent is given, and the date and signature(s) of the client (or authorised representative) and the person obtaining consent.
- b) Post-service care instructions, clearly explaining to clients the recommended actions after a procedure, including recognised precautions, signs of complications, follow-up requirements and emergency contact information; such instructions shall be provided in writing and in a language understood by the client and retained in the client record.
- c) Incident and adverse event reporting procedures, including documented methods for identifying, reporting, recording, analysing and responding to incidents or adverse events that occur in connection with the provision of services, as well as the responsibilities, timelines and escalation paths for reporting internally and to authorised regulatory authorities.

18 References

- 1) Healthcare Services Rules and Regulations of Bhutan, 2025, Ministry of Health, Bhutan.
- 2) ISO 9000:2015, Quality management systems — Fundamentals and vocabulary.
- 3) ISO 9001:2015, Quality management systems — Requirements.
- 4) National guideline on infection control and medical waste management, Ministry of Health, Bhutan.
- 5) WHO guidelines on hand hygiene in health care, World Health Organization.
- 6) WHO safe management of wastes from health-care activities, World Health Organization.
- 7) WHO practical guidelines for infection control in health care facilities, World Health Organization.

19 Annexes

Annexure A

Application for the establishment of Other Services Centre

(Please complete all sections in BLOCK LETTERS. Attach all required supporting documentation as specified in the guideline.)

A. PROPOSED CENTRE DETAILS

1. Name of proposed centre: _____
2. Type of service
 - Tattoo studio
 - Massage centre
 - Wellness centre
 - Other: _____
3. Scope of services proposed: _____

B. PROPONENT DETAILS

4. Proponent name _____
5. Legal status of proponent
 - Individual proprietor
 - Partnership
 - Registered company
 - Other: _____
6. Phone: _____ Email: _____
7. Authorised representative/ Contact person
 - Name: _____
 - Position: _____
 - CID: _____
 - Phone: _____ Email: _____

C. PREMISES DETAILS

8. Premises address: _____
9. Location map attached Yes No

D. BUSINESS AND OPERATIONAL PLAN

10. Attach the details covering the following:
 - 1) description and scope of services;
 - 2) organisational structure, roles and responsibilities; and
 - 3) estimated hours of operation and expected client volume.

E. INFRASTRUCTURE & LAYOUT DOCUMENTATION

11. Floor plan attached Yes No
12. Schedule of accommodation attached Yes No

13. Utilities documentation attached Yes No

F. INFECTION PREVENTION & CONTROL DOCUMENTATION

14. IPC documentation attached (*check all that apply*)

- Hand hygiene procedures
- Environmental cleaning and disinfection
- Linen/reusable materials management
- Instrument and equipment decontamination
- Sterilisation/high-level disinfection, if applicable
- Single-use disposable item use procedures

G. HUMAN RESOURCES DOCUMENTATION

15. List of personnel attached Yes No

16. Evidence of relevant qualifications and skills attached Yes No

H. EQUIPMENT & MATERIALS DOCUMENTATION

17. Inventory of major equipment and tools attached Yes No

18. Material safety data sheets, where applicable Yes No

I. WASTE MANAGEMENT PLAN

19. Waste management plan attached Yes No

J. OCCUPATIONAL HEALTH & SAFETY PLAN

20. Occupational health and safety plan attached Yes No

K. DECLARATIONS & UNDERTAKINGS

I, the undersigned, declare that:

- I/we will comply with all applicable laws, rules, regulations and standards relevant to the establishment and operation of the proposed other services centre;
- all information and documents submitted in this application are true, accurate and complete to the best of my/our knowledge; and
- I/we consent to inspection, monitoring, and regulatory oversight by the MoH or its authorised agents.

Signature: _____

Name: _____

Position: _____

Date: _____

For official use only

Date received: _____

Application fee receipt no. _____

Check the following documents are attached with this application:

- Proof of identity
- Business and operational plan
- IPC documentation
- Human resource documentation
- Equipment and consumables list
- Waste management plan
- Occupational health and safety plan
- Declarations and undertakings
- Other: _____

Received by:

(Name and Signature)

