GUIDELINES OF MINIMAL REQUIREMENTS FOR OUTPATIENT SURGICAL FACILITIES

Guideline document – Updated with current scientific evidence (2024–2025)

OUTPATIENT SURGERY FACILITY

Procedures that can be performed include those under topical, local, loco-regional, or truncal anesthesia with sedation according to the RASS scale from 0 to −2 (minimal to mild sedation). Current evidence supports outpatient surgery in ASA I–II patients and carefully selected ASA III patients, provided standardized risk stratification, enhanced recovery protocols, and emergency preparedness are in place.

If procedures cannot be safely performed under local or loco-regional anesthesia alone, a documented preoperative anesthesiology consultation is mandatory. The presence of an anesthesiologist or anesthesia-trained physician dedicated to the operating or emergency block is required whenever sedation beyond minimal levels is planned.

STRUCTURAL REQUIREMENTS

The facility must ensure the absence of architectural barriers limiting safe access, evacuation, and internal movement, in compliance with international accessibility standards.

The outpatient facility should preferably be located on the ground floor or within a building equipped with an elevator suitable for stretcher transport. Where stretcher elevators are unavailable, certified emergency transport systems equivalent to those used by emergency medical services are acceptable.

SURGICAL AREA

- Area/room for patient preparation with changing facilities
- Filter area/room
- Area/room for staff preparation communicating directly with the operating room
- Dedicated operating room with a minimum surface of 20 sqm, allowing safe equipment placement, staff circulation, and unobstructed emergency access

- Area/room for patient recovery and observation immediately adjacent to the operating room
- Storage cabinets for sterile materials and surgical instruments
- Separate area/room for washing and disinfection of instruments
- Area/room for sterilization of instruments if centralized or external sterilization services are not available

Evidence supports separation of clean and dirty pathways and proximity of recovery areas to reduce adverse events and improve response times.

OTHER ROOMS

- Area/room for administrative activities
- Waiting area with seating capacity appropriate to procedure volume
- Reception area ensuring patient confidentiality
- Examination and dressing room
- Staff changing room with lockers divided into clean/dirty compartments (may be shared in multispecialty facilities)
- Patient toilets proportional to activity volume, with at least one accessible toilet Staff toilet
- Dedicated area/room for healthcare waste
- Area for temporary storage of contaminated materials

TECHNICAL AND PLANT REQUIREMENTS

Adequate lighting and ventilation must be ensured in all clinical areas.

The operating room must be equipped with environmental controls ensuring:

- Temperature 20–24 °C
- Air exchanges ≥6/hour with fresh external air; ≥15/hour where sedation is used
- Relative humidity 40–60 %

The operating room is equipped with:

- Medical gas supply (oxygen and vacuum) or validated equivalent systems
- Seamless, washable, disinfectable, chemical-resistant flooring
- Smooth, washable wall surfaces up to at least 2 m

- Appropriate surgical instrumentation for the procedures performed
- Operating table with adjustable positioning
- Surgical lighting meeting luminance standards
- Dedicated anesthesia cart
- Refrigerator for temperature-sensitive medications with continuous monitoring and alarm
- Emergency electrical power supply and UPS systems must be available to maintain life-supporting equipment.
- The recovery area must include continuous patient observation capability, with visual and acoustic call systems.
- An emergency cart must be immediately available (see Annex). In facilities with multiple operating rooms, the emergency cart must be clearly marked and rapidly accessible.
- Adequate quantities of appropriate PPE must be maintained at all times.

Written protocols must exist for:

- Procurement, cleaning, disinfection, and sterilization of instruments
- Environmental cleaning and room turnover
- Safe disposal of healthcare and hazardous waste

ORGANIZATIONAL REQUIREMENTS

Staffing levels must reflect procedural complexity and case volume.

All clinical staff must maintain up-to-date certification in basic and advanced life support.

Minimum staffing includes:

- Medical Director responsible for clinical governance
- Appropriately credentialed specialist physicians
- Nursing staff trained in perioperative and recovery care
- Administrative staff

Operating rooms must not be used for non-clinical activities.

An operative register must be maintained documenting:

- Patient identification
- Diagnosis
- Operators
- Procedures with start and end times
- Type of anesthesia
- Immediate complications

Records must be stored in accordance with local legal and data-protection regulations.

A controlled drugs register must be maintained.

Each patient must have an outpatient medical record including personal data, medical history, ASA classification, investigations, procedure details, prescriptions, discharge criteria, and follow-up instructions.

Privacy and data protection regulations must be strictly observed.

Formalized protocols must cover:

- Patient selection and risk stratification
- Informed consent Local management of complications
- Emergency response and escalation
- Continuity of care with primary physicians
- Transfer to an acute hospital when required

Additional requirements for standalone facilities include:

- Medical availability for at least 24 hours post-procedure
- Written emergency management procedures
- Formal agreements with nearby hospitals
- Integration with local emergency medical services

ANNEX – EMERGENCY CART EQUIPMENT

The emergency cart must include equipment and medications necessary for airway management, cardiopulmonary resuscitation, anaphylaxis treatment, hemorrhage control, and advanced life support, in accordance with internationally accepted resuscitation guidelines.

REFERENCES

1.Liguria Regional Authority – Regional Government Resolution No. 589/2023 on the "Reorganization of Ambulatory Surgery Services"
2. Royal College of Anaesthetists. Guidelines for the Provision of Anaesthesia Services (GPAS), 2024.
3. Care Quality Commission (CQC). Regulation 12: Safe Care and Treatment, UK, 2023–2024.
4. National Institute for Health and Care Excellence (NICE). NG45, NG180, NG179.
5. ASA. Practice Guidelines for Moderate Procedural Sedation and Analgesia, 2018 (updated statements 2023).
6. WHO. Global Guidelines for the Prevention of Surgical Site Infection, 2018–2023 updates.
7. ESAIC. European Guidelines on Peri-operative Patient Safety, 2023.
8. AORN. Guidelines for Perioperative Practice, 2024.
9. Joint Commission International (JCI). Ambulatory Care Standards, 8th Edition.
10. CDC. Guidelines for Environmental Infection Control in Healthcare Facilities.
11. Middle East Health Authorities: DHA (Dubai), CBAHI (Saudi Arabia), DoH Abu Dhabi outpatient surgery standards.

INTERNATIONAL REGULATORY GUIDELINES' ALIGNMENT

UNITED KINGDOM (CQC):
CQC Key Lines of Enquiry (KLOEs): Safe, Effective, Caring, Responsive, Well-led. Emphasis on governance, incident reporting, infection control, medicines management, staffing, and duty of candour.

EU (ESAIC / NATIONAL REGULATORS):
ESAIC peri-operative safety standards, EU MDR equipment requirements, and national licensing frameworks. Supports outpatient surgery under risk-stratified pathways.

UNITED STATES (AAAASF / JCI / STATE BOARDS):
AAAASF Class A–B facility standards, ASA sedation guidelines, CMS ambulatory surgery center expectations, and Joint Commission International accreditation.

MIDDLE EAST (DHA / DoH / CBAHI):
Outpatient surgical licensing requirements in UAE and KSA, including emergency transfer agreements, on-call medical coverage, and facility accreditation readiness.