GOVERNMENT OF DUBAI

DUBAI HEALTH AUTHORITY

Standards for Endoscopy Services

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Health Policies and Standards Department

Health Regulation Sector (2019)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018, to undertake several functions including, but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice
- Managing patient complaints and assuring patient and physician rights are upheld
- Managing health advertisement and marketing of healthcare products
- Governing the use of narcotics, controlled and semi-controlled medications
- Strengthening health tourism and assuring ongoing growth
- Assuring management of health informatics, e-health and promoting innovation

The Standards for Endoscopy Services aims to fulfil the following overarching DHA Strategic Objectives and Program within the Dubai Health Strategy (2016–2021):

- Objective 1: Position Dubai as a global medical destination by introducing a value-based, comprehensive, integrated and high-quality service delivery system
- Objective 2: Direct resources to ensure happy, healthy and safe environment for Dubai population
- Strategic Program 10: Excellence & Quality, which promotes excellence in healthcare service delivery in Dubai while enhancing patient happiness, experience, satisfaction and trust

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts. HRS would like to acknowledge and thank these professionals for their dedication toward improving quality and safety of healthcare services.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

The purpose of this document is to assure provision of the highest levels of safety and quality of endoscopy services within DHA licensed health facilities at all times.

These standards have been developed to keep pace with the evolving healthcare needs and as per international clinical best practice. The standards include various aspects required to provide effective, efficient and safe endoscopy services. It includes the registration and licensure procedure requirements, healthcare professional requirements to provide the service, various aspects of safe patient care, equipment use and maintenance, disinfection of endoscopes, sedation requirements for endoscopy, emergency management of patients, infection control related to endoscopy service, use of personal protective equipment (PPE) and disinfection of endoscopes.

Endoscopy is a procedure where the inside of the body is examined using an instrument called an endoscope. An endoscopy can be used for diagnostic investigation, to assist perform certain types of surgeries or extract small samples of tissue for analysis, known as a biopsy.

Endoscopy procedures are a Consultant led service in a General Hospital or Specialty Hospital. Day Surgical Centres can provide Endoscopy procedures classified as 1 and 2 by the American society of anesthesiology (ASA). Endoscopic procedures could be done by DHA licensed consultant/specialist physicians who are privileged by the Medical Director and the privileging committee of the health facility aligned with their education, training, experience and competencies.

The physician should perform annually a minimum of 50 cases of Upper Gastric Endoscopy or 50 cases of Colonoscopy or 20 cases of ERCP to maintain the privileges. Every patient must be considered a potential

source of infection, and all endoscopes and accessory devices must be decontaminated with the same degree of rigor following an endoscopic procedure.

DEFINITIONS

Capnography is the monitoring of the concentration or partial pressure of carbon dioxide (CO_2) in the respiratory gases. Its main development has been as a monitoring tool for use during anaesthesia and intensive care.

Consultant led service is a service where a consultant retains overall clinical responsibility for the service, care professional team or treatment. The consultant will not necessarily be physically present for each consultant led activity but the consultant takes clinical responsibility for each patient's care.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Endoscope is a flexible tube with an attached camera that is inserted into the body through a small cut or an opening in the body such as the mouth that allows the physician to look at parts of the body that could not be seen any other way. The physician may use forceps (small tongs) and snares or others devices through the endoscope channels to operate or remove tissue for biopsy. Endoscopes are often used in the prevention, early detection, diagnosis, staging and treatment of diseases.

Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that enables your physician to examine the pancreatic and bile ducts. A bendable, lighted tube (endoscope) about the thickness of your index finger is placed through your mouth and into your stomach and first part of the small intestine (duodenum).

Endoscopic ultrasound (EUS) is a procedure that allows a physician to obtain either endoscopic images and/or ultra-sonographic images for information about the digestive tract and the surrounding tissue and organs, including the lungs. Consists of an endoscope with a miniaturized ultrasound device on the tip.

Endoscopy is a medical procedure performed with an endoscope to examine a patient's internal organs, acquire specimens and perform minimal or sometimes more advanced invasive procedures, without making large incisions.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Healthcare professional shall mean a natural person who is authorized and licensed by the Dubai Health Authority to practice any of healthcare professions in the Emirate.

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (Conscious Sedation) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Patient is any individual who receives medical attention, care or treatment by any healthcare professional or is admitted in a health facility.

ABBREVIATIONS

ACLS : Advanced Cardiac Life Support

AN : Assistant Nurse

ASA : American Society of Anesthesiologists

BLS : Basic Life Support

DHA : Dubai Health Authority

DM : Dubai Municipality

EMR : Endoscopic Mucosal Resection

ERCP : Endoscopic Retrograde Cholangiopancreatography

EUS : Endoscopic Ultrasound

HFG : Health Facility Guidelines

HPSD : Health Policy and Standards Department

HRS : Health Regulation Sector

ICU : Intensive Care Unit

IV : Intravenous

MOHAP : Ministry of Health and Prevention

PPE : Personal Protective Equipment

RN : Registered Nurse

UAE : United Arab Emirates

1. BACKGROUND

Endoscopy is an area of rapidly growing interest medicine because it is relatively a non-invasive procedure in which a tremendous amount of diagnostic data may be obtained. Endoscopy is the investigation of body cavities and organs by means the insertion of rigid or flexible tubes of varying diameter. At the leading end of these tubes, there is usually a source of light source, a means for conveying images to the operator and an access channel. The access channel allows insertion of air, fluids or instruments into the body or the removal of gas and liquids by suction. Many branches of medicine and surgery use this useful tool to investigate and treat their patients. There are many types of endoscopes. Depending on the site in the body and type of procedure, an endoscopy may be performed either a Specialist or Consultant physician. A patient may be fully conscious or anaesthetised during the procedure. The main parameters of endoscopy include, but not limited to:

Diagnostic

- Visualisation of the lining of the gut
- Biopsy of the lining of the gut
- Combined use of x-ray and ultrasound techniques

Therapeutic

- Removal of polyps or tumours by snare, EMR (Endoscopic Mucosal Resection) or microsurgery
- Insertion of stents (expanding wire cages) to treat obstruction
- Control of bleeding by injection, clipping, banding and the application of heat
- Tissue and ligament repair

2. PURPOSE

2.1. To assure provision of the highest levels of safety and quality of endoscopy services in Dubai Health Authority (DHA) licensed health facilities.

3. SCOPE

3.1. Endoscopy services authorized by DHA.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing endoscopic services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing endoscopy services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities aiming to provide endoscopic services shall comply with the DHA licensure and administrative procedures available on the DHA, Health Regulation Sector (HRS) website Health Regulation Sector.

5.3. Licensed health facilities opting to add endoscopy services shall inform HRS and submit an application to HRS to obtain permission to provide the required service.

5.4. The health facility should develop the following policies and procedure; but not limited to:

5.4.1. Patient acceptance criteria.

5.4.2. Patient assessment and admission.

5.4.3. Patient education and Informed consent.

5.4.4. Patient health record.

5.4.5. Infection control measures and hazardous waste management.

5.4.6. Incident reporting.

5.4.7. Patient privacy.

5.4.8. Medication management.

5.4.9. Emergency action plan.

5.4.10. Patient discharge/transfer.

5.5. The health facility shall maintain treatment protocols related to safe use of endoscopes which may include, but not be limited to the following:

5.5.1. Reprocessing of reusable equipment.

5.5.2. Establish protocol for safe use of chemicals used for cleaning and disinfecting.

5.6. The health facility shall provide documented evidence of the following:

5.6.1. Transfer of critical/complicated cases when required

5.6.2. Patient discharge.

5.6.3. Clinical laboratory services.

5.6.4. Equipment maintenance services.

5.6.5. Laundry services.

5.6.6. Medical waste management as per Dubai Municipality (DM) requirements

5.6.7. Housekeeping services.

5.7. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.8. The health facility shall have in place a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects.

5.9. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. Surgical and diagnostic endoscopic procedures shall only be performed in a General Hospital, Specialty Hospital or a Day Surgical Centre.

6.1.1. General Hospital and Specialty Hospital providing surgical and diagnostic procedure should be consultant led services.

6.1.2. Day surgical centres shall only provide endoscopic services to patients ASA 1 and 2 as per **Appendix 1 and 2**. Laparoscopic patients, patients with complicated health conditions, co-morbidities, systemic disease and emergency conditions shall be referred to a hospital setting.

6.2. The health facility should meet the health facility requirement as per the Health Facility Guidelines (HFG) Endoscopy Unit.

6.3. The health facility should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications.

6.4. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups.

6.5. The health facility design shall provide assurance of patients and staff safety.

6.6. The health facility shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

6.7. Day Surgical Centres opting to perform endoscopy services shall have ventilators and hemodynamic monitoring equipment on-site to perform necessary patient resuscitation.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

Staffing requirements to provide endoscopy service should be based on what is required to create a safe environment for the patient and to ensure the safe performance of the endoscopy procedures by healthcare professionals. Both patient and procedural factors should be considered in determining staffing requirements.

7.1. To conduct endoscopic procedures the physician should be DHA licensed consultant/specialist.

7.2. Surgical Endoscopy procedures should be a Consultant led service in a Hospital setting.

7.3. The Privileging Committee and/or Medical Director of the health facility shall privilege the physician aligned with his/her education, training, experience and competencies. The privilege shall be reviewed and revised as per DHA clinical privileging policy. To be privileged and maintain these privileges, to perform Endoscopic procedures, the physician shall fulfil the following criteria:

7.3.1. Have a recognised Fellowship or training from an established institution

7.3.2. The physician should perform annually a minimum of fifty (50) cases of Upper Gastric Endoscopy or fifty (50) cases of Colonoscopy or twenty (20) cases of Endoscopic retrograde cholangiopancreatography (ERCP) to maintain the privileges.

7.4. All healthcare professionals in the health facility shall hold an active DHA professional license and work within their scope of practice.

7.5. All healthcare professionals who provide patient care shall maintain a valid Basic Life Support (BLS) certification.

7.6. At least one healthcare professionals working in Endoscopy procedure room should maintain a valid training/certification in Advanced Cardiac Life Support (ACLS).

7.7. A written policy on staff training along with the type and frequency of core competency assessment should be documented and monitored on an annual basis.

7.8. Adequate Registered Nurses (RNs), Assistant Nurses (ANs) and/or Operation Theatre Technicians should be present to assist with the technical aspects of the endoscopic

procedures. Complex interventional procedures, such as Endoscopic ultrasound (EUS) and ERCP may require additional staff for efficiency, safety and quality.

7.9. The health facility shall employ a biomedical engineer or maintain a contract with a certified maintenance company to ensure safety and efficiency of equipment.

8. STANDARD FOUR: PATIENT CARE

8.1. Physicians administering sedation must have the knowledge and skills to recognize when the sedation level becomes deeper than planned and to manage and support patients' cardiopulmonary responses to sedation accordingly.

8.2. The endoscopy setup shall be capable of providing the required level of sedation/anaesthesia.

8.3. The patient must sign the informed consent that elaborates risks, benefits and alternatives before the endoscopic procedure. The minimum criteria for informed consent is in the **Appendix 3.**

8.4. A comfortable treatment environment should be provided in the endoscopy facility and assure patient privacy.

8.5. Patient Assessment

8.5.1. A comprehensive patient assessment process shall be achieved with the support of a multidisciplinary team and based on clinical and priority needs of each individual patient.

8.5.2. The patient assessment shall include, but not be limited to, medical history, physical, social, psychological and anaesthetic assessment (if applicable) and identification of patients.

8.5.3. Before starting the endoscopic procedure, the patient, staff and performing physician should verify the correct patient and procedure to be performed.

8.5.4. When necessary, the health facility shall have the ability to stabilize critically ill patients and transfer them to a higher level of care if the health facility is unable to manage the patient on-site.

a. The health facility shall have a written and signed transfer agreement with a hospital capable of managing endoscopy related complications. This transfer agreement shall detail the transfer plan of the patients.

8.5.5. Discharge plan should start at admission and include various personnel, information and resources. Considerations for discharge preparation should include, but not be limited to:

a. The pickup person.

b. Travel distance to home.

c. No driving policy.

d. Environmental conditions, such as stairs, access to toilet or bedroom.

e. The carer's/authorized persons contact details and their awareness of possible issues and requirements following discharge.

f. Contact numbers after discharge, such as the doctor or emergency contact

g. Discharge arrangements.

h. Healthcare professionals should use a formal risk assessment process.

i. Patient monitoring should be performed before the procedure, after administration of sedation, at regular intervals during the procedure, during initial recovery and before discharge.

j. Food appropriate for the patient and consistent with patient's condition and clinical care shall be provided.

9. **STANDARD FIVE:** EQUIPMENT USE AND MAINTENANCE

The life of an endoscope is in most cases determined by the quality of its maintenance.

9.1. Endoscopes should be stored safely, hanging vertically in cupboards through which air can be circulated and should be based on the manufacturer's recommended shelf life for storage and reprocessing.

9.2. All endoscopic instruments should be checked before use. The RN/AN should set up the endoscopic equipment with water bottle and other accessories suitably cleaned and disinfected the endoscope.

9.3. The physician is responsible to check the final status, readiness, functionality and safety of the equipment.

9.4. All equipment shall be properly calibrated and adjusted.

9.5. All repairs and maintenance shall be accurately documented.

10. STANDARD SIX: DISINFECTION OF ENDOSCOPES

Every patient must be considered a potential source of infection, and all endoscopes and accessory devices must be decontaminated with the same degree of rigor following an endoscopic procedure.

10.1. All healthcare professionals providing endoscopy services should be trained in infection control and adhere to standard infection control procedures.

10.2. Endoscope reprocessing comprises of two basic components, which are:

10.2.1. Manual cleaning, including brushing and exposure of all external and accessible internal components to a low-foaming, endoscope-compatible detergent

10.2.2. Automatic disinfection, rinsing and drying of all exposed surfaces of the endoscope.

10.3. All endoscopes shall be stored in a way that prevents re contamination and promotes drying (e.g., hung vertically)[1, 2]

10.4. Endoscope disinfection or sterilization with a liquid chemical sterilant involves a few steps that are mentioned in **Appendix 4** [3]

[1] Drying the endoscope is essential to reduce the chance of recontamination of the endoscope by microorganisms that can be present in the rinse water.

[2] There are requirements for reprocessing after storage for long periods (may be more than 24–72 hours) as recommended by the manufacturers specifications.

[3] Note: For further information on reprocessing of scopes, refer to the Multisociety guideline on reprocessing flexible GI endoscopes: 2016. American Society for Gastrointestinal Endoscopy https://www.asge.org/docs/defaultsource/education/practice_guidelines/2016_ms_reprocessing_flexible_endoscopes.pdf?sfvrsn=8 .

11. **STANDARD SEVEN:** ENDOSCOPIC SEDATION

The choice of specific sedation agents and the level of sedation targeted should be determined by the physician performing the procedure on a case-by-case basis in consultation with the patient.

11.1. Sedation related environment

11.1.1. A health facility providing endoscopy services shall comply with applicable federal laws and local regulations regarding licensure and/or certification of all staff involved in the administration and monitoring of sedation and document training and competencies.

11.1.2. The health facility should establish discharge criteria. Patients who received intravenous (IV) sedation during an endoscopic procedure should be discharged in the presence of a responsible healthcare professional.

11.1.3. A focused history and physical examination, including the patient's current medications etc., should be completed before the start of the procedure.

11.2. Sedation related equipment

11.2.1. A qualified biomedical engineer shall examined and verify all sedation-related equipment as per manufacturer's specifications before initial use and at regular intervals to ensure proper working condition.

11.2.2. The procedure room shall maintain electronic equipment to monitor and display pulse, blood pressure, oxygen saturation, electrocardiogram, source of oxygen and suction for the mouth.

11.2.3. A written policy for equipment checks and maintenance shall be in place and a log to monitor compliance should be maintained.

12. STANDARD EIGHT: PATIENT MONITORING

12.1. All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (e.g., type of sedation, duration and complexity of procedure and patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery and just before discharge.

12.2. The health facility shall have procedures in place to rescue patients who are sedated deeper than intended.

12.3. When moderate sedation is targeted, the healthcare professional assigned responsibility for patient monitoring may perform brief, interruptible tasks. Minimal monitoring is required which could include electronic assessment of blood pressure, respiratory rate, heart rate and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.

12.4. When deep sedation is targeted, the healthcare professional responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.

12.4.1. Capnography in EUS, ERCP and colonoscopy is used to assess adequacy of ventilation to reduce the incidence of hypoxemia and apnea. Capnography may be

considered for the performance of endoscopy under deep sedation and use of CO2 insufflation.

12.5. Documentation of the clinical assessments and monitoring data during sedation and recovery is required.

13. STANDARD NINE: EMERGENCY MANAGEMENT

13.1. Appropriate pharmaceutical agents, oxygen, oral suction, laryngoscope, ambu bag and defibrillator should be readily available in the health facility.

13.2. The health facility should ensure periodic training and education for staff in the use of equipment for emergency management. Training and assessment of competency should be documented as per the requirements of the training provider.

14. STANDARD TEN: INFECTION CONTROL

14.1. In addition to meticulous endoscope reprocessing, a specific infection prevention plan and monitoring should be implemented to prevent transmission of pathogens.

14.2. Active infection prevention surveillance programs and ongoing educational and competency evaluation of staff regarding activities within the pre-procedure, intra-procedure and post-procedure phases are necessary for overall safety of patients and healthcare professionals.

14.3. Written policies and procedures regarding infection control for a endoscopic facility should be documented.

14.4. Hand hygiene should be performed before patient contact (even if gloves are to be worn), after patient contact and before exiting the patient care area, after contact with blood, body

fluids or contaminated surfaces, before performing invasive procedures and after glove removal.

14.4.1. Use of soap and water is required when hands are visibly soiled.

14.5. Environmental cleaning of surfaces with a disinfectant is mandatory, especially for surfaces that are most likely to become contaminated with pathogens, such as those in close proximity to the patient (e.g., side rails) and other frequently touched surfaces. Policies and procedures should address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious material. The health facility should:

14.5.1. Maintain material safety data sheets for all chemicals used for cleaning and disinfection. These sheets should detail the safe and proper use and emergency protocol for a chemical. Material safety data sheets should be used for training staff on each chemical's safe use.

14.5.2. Follow the manufacturer's directions for surface disinfection of patient care items.

a. Appropriate contact time of disinfectant to achieve germicidal kill should be followed.

b. Alcohol should not be used to clean environmental surfaces.

14.5.3. Properly clean and disinfect surfaces that are frequently touched like endoscopy keyboards, video monitors, consoles or dirty equipment in the endoscopic procedure area at the beginning of the day, between cases and during terminal cleansing.

15. STANDARD ELEVEN: PERSONAL PROTECTIVE EQUIPMENT (PPE)

15.1. The use of PPE is dictated by patient traffic patterns, location of care and the potential of direct contact with patients and their bodily fluids during specific activities.

15.2. Healthcare professionals directly engaged in endoscopic procedures in which splash or contamination could occur shall wear gloves, face/eye shields and impervious gowns.

15.3. Healthcare professionals shall remove and appropriately, discard used PPE before leaving the procedure room.

15.4. Contaminated clothing should be placed in a bag and identified as potential biohazardous. The bag with the contaminated clothing should be sent to a laundry capable of cleaning and disinfecting them.

16. STANDARD TWELVE: MEDICATION & MEDICATION ADMINISTRATION PRACTICES

16.1. The health facility shall maintain written policies detailing the methods of drug storage and monitoring of drug inventory and expiration dates. It should also maintain documentation of compliance with these policies.

16.2. A qualified and licensed healthcare professional (physician/pharmacist/RN) shall oversee the medication usage.

16.3. Medication shall be securely stored under environmental conditions consistent with the manufacturer's specifications. The use of single-dose vials for all sedative and analgesic medications is strongly recommended.

16.4. Controlled substances shall be stored in a single locked cabinet and a daily medication log shall be maintained.

16.5. Storage and disposal of controlled drugs shall be compliant with federal laws and local regulations.

16.6. Medication should only be given only under the order of the supervising physician when applicable.

16.7. Reversal agents for opioids and benzodiazepines should be readily available.

16.8. A written policy shall be in place for the identification, documentation and review of adverse drug reactions.

16.9. The health facility providing endoscopic services maintains a policy on proper storage and handling of anaesthesia agent, the health facility must abide by the Ministry of Health and Prevention (MOHAP) regulation on storage, handling and records maintaining of narcotic and controlled medications.

16.10. To prevent pathogens transmission resulting from improper use or reuse of syringes, multiple dose drug vials and IV equipment certain standards should be adhered to:

16.10.1. Preparing medications for multiple patients should be done in an area away from direct patient care or procedure rooms.

16.10.2. All medications should be appropriately labelled, including those used for sedation, unless the medication is for immediate use (prepared and administered immediately without leaving the provider's hand).

16.10.3. Medications either marked on the container or noted in the package insert as "single patient use" should be used for a single patient only and any remaining drug should be discarded.

16.10.4. New fluid administration sets (e.g., IV tubing) Units should be used for each patient.

16.10.5. Aseptic technique (i.e., cleansing the access diaphragms of medication vials with 70% alcohol before inserting a device in the vial) should be used to prepare and administer injections. By using Single-dose vials, ampules, bags, or bottles of IV solution should be used for a single patient only.

16.10.6. Use of a single-dose vial is preferred over multiple dose vials, particularly when medications are administered to multiple patients.

16.10.7. If a multiple-dose vial are used for more than one patient, they should remain in a centralized medication area and should not enter the patient procedure room. These should be dated when opened and discarded according to protocols, in compliance with nationally MOHAP accepted guidelines and those published by the Centers for Disease Control and Prevention.

16.10.8. Re-use of a syringe to enter a medication vial or solution, even with a new needle shall not be permitted.

16.10.9. The same syringe shall not be used to administer medications to multiple patients regardless of whether the needle is changed or an intervening length of IV tubing is used.

16.10.10. Used syringes and needles should dispose of at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.

16.10.11. A clearly defined policy for the management of sharps and sharps-related injuries, including the reporting of blood and body fluid exposures should be developed.

16.10.12. A log of sedation medications wasted between patients that can be used to reconcile used and wasted vials at the end of the day should be maintained.

16.10.13. If tubes of lubricant are used for more than one examination, appropriate infection control habits should be observed and any tube that has potentially been contaminated should be discarded.

17. STANDARD THIRTEEN: REUSABLE MEDICAL EQUIPMENT

17.1. The reprocessing protocol of reusable medical equipment such as endoscopes and endoscopic accessories must be strictly followed.

17.2. Final rinse water of the endoscope washer disinfector and rinse sample cultures for endoscopic channels and water bottle should be tested on a monthly basis.

17.3. These policies should be a part of the unit's policies and procedures and core competency assessment.

17.4. Single-use devices as determined by the manufacturer label or packaging insert should not be reprocessed.

18. STANDARD FOURTEEN: TERMINAL CLEANSING

Terminal cleansing involves the cleaning of surface to remove soil and biofilm, followed by proper disinfection. This is a two-stage process, requiring use of distinct cleansing agents and disinfectants.

18.1. The endoscopy facility should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.

18.2. Agents for terminal cleansing should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.

18.3. Before the first case of the day, staff should verify that all procedural and recovery areas have been properly cleansed.

18.4. A training and competency assessment program should be in place for staff members who are involved in terminal cleansing to ensure proper and safe handling and use of the chemicals.

19. STANDARD FIFTEEN: KEY PERFORMANCE INDICATORS (KPIs)

19.1. Clinical Quality- Potential preventable Hospitalization

19.2. Clinical Quality- Rate of Unplanned readmissions within 28 days

19.3. Patient Happiness- Average waiting time for Elective Surgery

19.4. Patient Happiness- Recommendation to others

19.5. Patient Safety – Rate of 30 day mortality after surgery

19.6. Patient Safety – Rate of Medical Errors

19.7. Patient Safety – Rate of Medication Errors

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APPENDICES

APPENDIX 1: ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

ASA PS Classification	Definition	Examples, include but are not limited to:
ASA I	A normal healthy patient, without organic, physiologic, or psychiatric disturbance	Healthy patient with good exercise tolerance, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease, anaemia, pregnancy
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, CHF, Stable Angina, old MI, COPD, Bronchospastic disease with intermittent symptoms, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, chronic renal failure, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis, unstable angina, Symptomatic COPD, Symptomatic CHF, Hepatorenal failure
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction, sepsis syndrome with hemodynamic instability, Hypothermia, Poorly controlled Coagulopathy
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	
E	This modifier is added to any of the above classes to signify a procedure that is being performed as an emergency and may be associated with a sub optimal opportunity for risk modification	

Note 1: The American Society of Anesthesiologists' Physical Class System was designed to describe the patient's current health status. As such, it is one of the most important factors used to assess the overall perioperative risk.

Note 2: Level III-VI patients are not permitted in DSC setting.

APPENDIX 2: DEFINITION AND LEVELS OF SEDATION/ANALGESIA*

	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
	Minimal Sedation Anxiolysis	**Moderate Sedation/ Analgesia ("Conscious Sedation")**	**Deep Sedation/ Analgesia**	**General Anesthesia**
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Level 1. Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Level 2. Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care (MAC) does not describe the continuum of depth of sedation; rather it describes, a specific anaesthesia service in which anesthesiologists has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.

** Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Level 3. Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Level 4. General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue***

patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

APPENDIX 3: MINIMUM REQUIREMENTS FOR INFORMED CONSENT FORM

Informed Consent Form For Patients
Name of Healthcare Professional: _____ **Name of Health Facility: _____** **Name of Patient: _____ File No: _____** **This Informed Consent Form has two parts:** • **Information Sheet (to share information about the treatment with you)** • **Certificate of Consent (for signatures if you agree to go ahead with the treatment)** ***You will be given a copy of the full Informed Consent Form*** **PART I: Information Sheet** **Introduction:** I, Dr. _____ with license No:_____ should be performing the _____treatment/ procedure on Miss/Mrs./Mr._____ aged _____years, on date _____. **<u>Description of the Procedure and Process</u>** Describe to the patient or customer, the procedure and what will happen on a step-by-step basis. The patient should be informed that procedure is newly introduced and the amount of supporting research and study available.

Side Effects

Potential patients should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

Complications

Inform and explain any possible complications that could be caused as a result of the treatment.

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Benefits

Mention only those activities that will be actual benefits of the treatment.

Confidentiality

Explain how the clinical team will maintain the confidentiality of data, especially with respect to the information about the patient including photography and videography.

Right to Refuse treatment/procedure

This is a reconfirmation that the patient has the right to refuse the treatment.

Alternatives to clinical procedure or treatment

It is important to explain and describe the established standard treatment or procedure for the patient's condition.

Financial Implications

All procedures/treatments provided that are not covered by insurance or which may require the patient's full payment or co-payment.

PART II: Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the treatment and be followed by a statement similar to the one in bold below. The healthcare professional performing the treatment and the person going over the informed consent should sign the consent.

Example:

Patient Consent statement

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to undergo tis treatment and understand that I have the right to withdraw from the procedure or treatment at any time without in any way affecting my medical care.

Name of Patient: _____

Signature of Patient:_____ Date: _____

Witness statement

I have accurately read or witnessed the accurate reading of the consent form to the potential patient, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____

Signature of witness: _____ Date: _____

Healthcare Professional Declaration:

I have adequately explained to the patient about the procedure along with risks, adverse effects and the standard alternatives that are available for the procedure. I have permitted time and opportunity for the patient to ask questions and all questions have been answered to my knowledge

Name of healthcare professional: _____

Signature of healthcare professional : _____ Date: _____

APPENDIX 4: ENDOSCOPE PROCESSING

Step	General recommendations
Precleaning	• Preclean immediately
Cleaning	• Always perform leak testing and block testing before immersing the endoscope in a detergent or soap solution, as this may help prevent expensive repairs later
Rinsing	• Always rinse between cleaning and disinfection
Disinfection	• Always immerse the endoscope and valves in a disinfectant solution of proven efficacy • Always irrigate all channels with a syringe until air is eliminated, to avoid dead spaces • Always observe the manufacturer's recommendations regarding the minimum contact times and correct temperature for the disinfection solution • Always observe the manufacturer's recommendations regarding compressed air values • Always remove the disinfection solution by flushing air before rinsing • Always determine whether the disinfectant solution is still effective by testing it with the test strip provided by the manufacturer
Final rinsing	• Always discard the rinse water after each use to avoid concentration of the disinfectant and thus damage to mucosa • Never use the same container for the first and final rinsing
Drying	• Always dry the endoscope properly before storage to prevent microorganism growth in the endoscope channels
Storage	• Never store in a transport container