Name of Policy: Endoscope Reprocessing Policy Number: 3364-144-02 Department: Endoscopy Approving Officer: Chief Nursing Officer (CNO) Responsible Agent: Director, Surgical Support Services Scope: The University of Toledo Medical Center	 Effective Date: 6/1/2023 Initial Effective Date: August 28, 2017
___ New policy proposal ___ Minor/technical revision of existing policy	_x_ Minor revision of existing policy ___ Reaffirmation of existing policy

(A) Policy Statement

This policy provides the process for high level disinfection of flexible endoscopes and other semi-critical medical devices used in the Endoscopy Department.

(B) Purpose

The purpose is to provide standardization for decontaminating and disinfecting semi critical equipment and reducing the risk of spreading infection.

(C) PROCEDURE

All endoscopes and semi-critical medical devices will undergo reprocessing after each use. Endoscope reprocessing includes the following steps according to the manufacturer's instructions for use and AAMI ST91:2021 practice recommendations:

1. Point-of-use cleaning
2. Leak testing
3. Manual cleaning
4. Visual Inspection
5. Channel Check (per schedule and as needed)
6. High level disinfection (manual or automated)
7. Drying
8. Proper Storage

(D) Guidelines

1. Personnel responsible for reprocessing endoscopes will receive education and competency verification regarding cleaning, disinfection, and storage of flexible endoscopes. This will be provided upon hire and on an annual basis, and whenever new equipment or products are acquired. Any breach in the cleaning process will require retraining and/or reassignment until competency is confirmed. Competencies will be documented in personnel files. Each endoscope's instructions for use (IFU) are readily available to personnel in the work area.

2. Personnel will don personal protective equipment (PPE), including a fluid-impervious gown with sleeves, fluid-resistant face mask, face shield or goggles, hair covering, and nitrile exam gloves during point-of-care pre-cleaning. Reprocessing personnel working inside the decontamination room will wear the same PPE but use general purpose utility gloves instead to cover forearms during leak-testing and decontamination of endoscope equipment. PPE worn during reprocessing will be removed properly and hands washed before donning clean PPE to handle disinfected endoscopes. Personnel will remove PPE and wash hands when leaving the room and between contaminated endoscopes.

3. Adverse events including exposure of a patient to potential infection, harm or injury will be immediately reported to management or House Supervisor and entered into the Patient Safety Net. Steps must be taken to maintain the patient's safety and prevent further injury or illness. Remove faulty equipment or devices, label appropriately with Biomed card, and send for repair. If applicable, the "I'm sorry" protocol will be initiated as per policy #3364-100-60-10 Communication of Serious Adverse Events.

4. If there is ever any question of whether an endoscope is clean or dirty then it is to be assumed dirty and must be reprocessed.

(E) Steps to Workflow

1. Reprocessing begins with point-of-use cleaning. It is important to follow the manufacturer's most current IFU for each endoscope. Personnel must be wearing PPE as indicated above. Immediately disassemble appropriate parts (if any). Wipe down the endoscope with the appropriate sponge as well as irrigate channels per manufacturer's instructions. Point-of-use cleaning is vital to soften, moisten and remove organic debris.

2. Carefully place endoscope into the provided leak-proof puncture-proof bin, place red biohazard cover on bin, and apply sticker with staff name and time point-of-use cleaning completed on cover where it can be seen by reprocessing personnel, then transport the endoscope horizontally to the decontamination room.

3. Perform a leak test according to the manufacturer's most current IFU, and visually inspect the endoscope for damage. If a leak or damage is detected, follow Guideline for Handling Damaged Endoscope Equipment. Notify Biomedical Technical Support.

4. Manually clean the endoscope according to the manufacturer's most current IFU. Use detergent approved for endoscope cleaning at the recommended concentration and temperature. Cleaning solution will be changed after each scope.

5. Rinse, wipe dry, and inspect with lighted magnification for cleanliness and damage. Scope Buddy Plus flushing aid is to be used for every endoscopic retrograde cholangiopancreatography (ERCP) and linear endoscopic ultrasound (EUS) endoscope reprocessing. All other endoscopes complete the flushing cycle using Medivators TM automated endoscope reprocessor but can utilize the Scope Buddy Plus for additional flushing as needed.

6. Regular biological testing of endoscopes will be performed after manual cleaning and before high level disinfection to validate the cleaning process has been conducted properly. ERCP, EUS, EBUS, and bronchoscopes will be tested after every use. All other

scopes will be tested on a monthly rotation but can be tested at any time to validate the cleaning process. Results for all testing will be recorded on the Channel Check™ log sheet.

7. High-level disinfection (HLD) will be completed on all endoscopes to reduce microbial contaminants according to the manufacturer's most current IFU. HLD can be done either manually using Revital-OX RESERT™ or the Medivators ™ Advantage Plus automated endoscope reprocessing system which completes the following steps during a full cycle:
    a. Leak test (continuous)
    b. Flush rinse
    c. Wash
    d. Post rinse
    e. High level disinfection
    f. Flush rinse
    g. Final rinse
    h. Vent (alcohol flush and forced air)

    Follow the manufacturer's instructions when using Revital-OX RESERT™ to disinfect endoscopes and accessories including appropriate rinsing, flushing with alcohol and purging with air. Record required information in HLD log for every item reprocessed.

8. Document all quality monitors in the log if applicable. AER documentation will be captured and stored electronically.

9. Dry equipment a minimum of 10 minutes using Dri-Scope Aid™ after AER or manual HLD, and dry externally according to manufacturer's IFUs.

10. Store endoscopes in cabinets approved for use with endoscopes. All endoscopes must hang in a neutral position paired with a mesh bag containing caps and accessories. Length of storage is seven days per SGNA recommendations and internal risk assessment. Endoscopes will be reprocessed before use if stored longer than seven days.

Each step is detailed in the Reprocessing Flexible Endoscope guidelines located on the University of Toledo Medical Center Nursing Guidelines website:
http://www.utoledo.edu/policies/utmc/nursing/guidelines/endoscopy/index.html

References:
Flexible and semi-rigid endoscope processing in health care facilities, 2021. ANSI/AAMI ST91.
Klacik, S. New AAMI standard for endoscope reprocessing (2015). *OR Manager*, 87568047, vol. 31, issue 9.
Endoscope cleaning and high-level disinfection learning guide, 2017. Society of Gastroenterology Nurses Association, 6th edition.

Approved by: _/s/_____ _____ Kurt Kless, MSN, MBA, BSN, RN, NE-BC Date Chief Nursing Officer *Review: Policy & Standard Committee, ,8/2017, 7/2020, 6/2023* *Revision completed by: Carol Bates, MSN, Ed, RN, 7/2020, 6/2023*	**Review/ Revision Date:** **8/2017** **7/2020** **6/2023** **Next Review Date:** 6/2026
Policies Superseded by This Policy: New	