

Support for Monitoring the Cleaning Process for Flexible Scopes

1. A 2003 multi-society position paper states: “**Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use.**” (*Gastrointestinal Endoscopy*, Volume 58 No.1; page 5)

2. **SGNA on Quality Assurance** “Each setting where gastrointestinal endoscopy is performed **must have an effective quality assurance program with special emphasis on cleaning and high level disinfection of flexible endoscopes.** Elements of the quality assurance program include supervision, training, annual competency review, methods of assuring the availability of appropriate equipment and supplies, and procedures for reporting infections... There must be a policy of invariable adherence to the reprocessing protocol. The protocol and its implementation should be reviewed periodically to assure that it is being followed routinely and that there is no new information that would require a modification....”¹

3. Highlights of **AAMI ST 79**:

- “Some types of mechanical cleaning equipment are designed to clean and/or disinfect specific kinds of medical devices, such as endoscopes... Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs...(7.5.3.3)”
- AAMI realizes that the efficacy of any high-level disinfection/sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bio-burden before high-level disinfection/sterilization.
- **Section 10.2 and ANNEX D states**“...Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices...”
- “**Current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm²; carbohydrate, < 1.8 µg/cm²; hemoglobin, < 2.2 µg/cm²; sodium ion, < 1 µmole/cm²; and endotoxin, < 2.2 EU/cm² in the biopsy/suction channel...(Section - D.2 Markers)**”
- Staff qualifications, training, and continuing education are important: “... Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented....” (Section 4.3.1)
- Regarding verification of the cleaning process: “... processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. **Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically....” (Section 7.7.5)
- “Furthermore, **visual inspection is not possible for the inner components of medical devices** that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). **Ideally, cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and inner housing and channels of medical devices,** (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters (e.g., temperature)...”²

4. Excerpts from published articles:

- *57% of centers that process scopes were not in compliance with basic national standards.*³

- ***“Our findings underline the potential for blood fixation, not only by glutaraldehyde, but also by peracetic acid, and support the evidence that effective cleaning should precede the chemical disinfection.”***⁴
- 53% of biopsy ports valves exhibited some form of debris or potential contamination after cleaning.⁵
- *“Company blames bronchoscope infections on poor cleaning.”*⁶
- Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to **thoroughly manually clean equipment prior to** any manual or automated disinfection or sterilization process.⁷
- “It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection; you don’t dry the scope; inadequate cleaning; or somebody forgot to clean the biopsy channel. It has been more human error than anything else... Rules No.1, 2 and 3 are to educate the people who are cleaning the scopes--how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning.”⁸
- In one case two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed. Only two hours had elapsed between the first patient and the last, so even if samples had been taken immediately after the first patient, traditional microbiology results would not have been available in time to prevent cross-infection.⁹

JCAHO¹⁰

In standard E.C.6.20 it states that medical equipment is maintained, tested and inspected

AORN¹¹

- 22.a.2 – page 442 – “...protein indicators are commercially available to assist with evaluation..”
- 22.a.4 – page 442 – “..when investigating surgical infections, documentation of the cleaning process of instruments should be reviewed...”
- RP 19 – page 440- “ ...competency, education, training...should be documented”
- RP 22.a – page 442 – “..testing washer decontaminators on a regular basis verifies that the equipment is functioning properly..”

FDA¹²

The FDA, AAMI and other regulatory bodies recommend that any simulated-use testing be done with a surrogate device that closely approximates the actual types of soils the instrument is to be exposed to in clinical use. Further, the surrogate device should be made of the same type of material as the instrument it represents.

Healthmark¹³

Healthmark is the only company with comprehensive tests for this purpose - tests to measure water temperature, water quality, cleaning efficiency, and directly test residual soil on instruments- the TOSI: dried blood soil on a stainless coupon is directly analogous to dried blood on a stainless instrument.

This document summarizes AAMI, AORN, JCAHO standards and guidelines and various published articles. Please note that AAMI, AORN, JCAHO and the articles are copyright material, to read the complete text of these standards or articles please go to their web site and purchase the actual standards and guidelines or articles.

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- ¹ <http://www.sgna.org/resources/guidelines/Infection.html>
 - ² ANSI/AAMI ST79:2006 and A1 & A2 ; page 142;and other sections as noted
 - ³ Infection Control and Hospital Epidemiology ; Volume 23 ; 2002
 - ⁴ Kampf G,Bloss,Martiny H;Surface fixation of dried blood by glutaraldehyde and peracetic acid;JHI; June 2004; 57(2): 139-143
 - ⁵ Endonurse 12/6
 - ⁶ 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html
 - ⁷ <http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf>, page 1
 - ⁸ page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005
 - ⁹ *The New England Journal of Medicine* **337**, 237-240 (1997).
 - ¹⁰ www.jcaho.org
 - ¹¹ www.aorn.org/psrp ; 2009
 - ¹² <http://www.artificialtestsoil.com/FDAreferencePage.htm>
 - ¹³ <http://www.healthmark.info/proformance.html>