



Ethical Issues in Medical Device Processing



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Objectives

- Discuss ethics today and its impact on processing reusable medical devices and endoscopes.
- Review a suggested Code of Ethics for processing personnel.
- Discuss specific ethical issues and how to resolve them.



Background

- “Healthcare professionals may face ethical issues such as conflicts of interest, distortion of medical facts, exorbitant or inconsistent billing, poor privacy and security of patient records and information, and compliance with local, state, and federal health regulations.
- Because noncompliance with healthcare legislation related to ethics can directly result in harm to patients, healthcare employers should provide ethics training and policies for their workers.
- These courses and policies explain the ethical issues that healthcare workers might encounter, why they exist, and how to deal with them.
- **The penalties for not following the guidelines set in these training courses and policies are sometimes severe: workers could face suspension, fines, loss of their medical license (if they have one), or lawsuits and jail time, depending on whether the worker violates employer or licensing body ethics policies or ethics legislation.”**

*Steven Coughlin, author of Ethical Issues in Epidemiologic Research and Public Health Practice, asserts that “ (Coughlin, 2006)

DEFINITIONS

- **Ethics** - the discipline dealing with what is good and bad and with moral duty and obligation.
- **Ethical actions** - actions which conform to accepted and professional standards of conduct.
- Ethical actions can be complicated by individual beliefs, knowledge base of the individual and their work ethic.



DEFINITIONS



- **MORALS** - concerning or relating to what is right and wrong in human behavior. Based on what you think is right and good.
- **UNETHICAL** - professional conduct which fails to conform to moral standards or policies.
- **PROFESSIONAL ETHICS** - principles of conduct governing an individual or group.

DEFINITIONS

- A **regulation** is a principle, rule, or law designed to control or govern behavior. Compliance with a regulation is mandatory (i.e., required by law).
- A **standard** is an established norm determined by opinion, authority, research, and/or theory. Examples are the American National Standards developed by the Association for the Advancement of Medical Instrumentation (AAMI). Although compliance with AAMI standards is not legally required (except when an individual state health department adopts these standards as regulations), AAMI standards for flexible endoscope processing, and other types of sterile processing activities are recognized as the primary measure of good practice.
- **Recommended practices and guidelines** are statements of sound principles of practice that are based upon scientific data and the opinions of experts. Compliance is not legally required, but recommended practices reflect accepted professional practices.



AAMI Documents

- All of the “ST” documents (e.g. ST-70) are national standards
- Recognized as best practices to provide a quality standard of care
- Due to the process of development, are widely recognized in a court of law
 - Guidelines and Recommendations use different methods of development for their documents
 - Not usually peer reviewed or put through a lengthy review process with continued input from the Committee members and the public
- Provides a reference for practice often cited in legal proceedings





ETHICS TODAY

What we do and how we do it affects the lives of everyone.

No individual or group is untouched.

Need to re-affirm our moral obligation to **DO THE RIGHT THING.**

PROFESSIONAL CODES OF ETHICS



American College of Healthcare
Executives



Dental Hygiene Practice



Nursing



Where is the Sterile Processing or
Endoscopy Processing Code of
Ethics?

SUGGESTED CODE OF ETHICS

- ✓ Always act in the best interests of the dignity, reputation, and good standing of the profession, applying professional judgment and acting responsibly in all matters related to patient care.
- ✓ Always act with courtesy and consideration to all those with whom you have to deal, including fellow professionals.
- ✓ Always comply with regulations and professional standards regarding safety and processing issues.
- ✓ Communicate clearly and concisely; remember that communication is a two-way process and that listening is critical to the process.

SUGGESTED CODE OF ETHICS

- ✓ Maintain your continuing education and certification by attending continuing education programs and retaining certificates for verification of program content and of your attendance.
- Identify safety and/or risk management issues and report them immediately.
- ✓ Never disclose confidential information about a patient.
- ✓ Never disclose confidential information about happenings at the facility; there could be legal implications.

SUGGESTED CODE OF ETHICS

- ✓ If you make a mistake, try to minimize it and own up to it so that corrective action can be taken.
- ✓ Seek total quality management for all stages of a process.
- ✓ Report any instances of facility property damage or theft and do not participate in it.
- ✓ Treat co-workers with dignity and respect as you would like to be treated.
- ✓ Accept constructive criticism as part of your professional growth.
- ✓ Accept changes in work schedules when they are dictated by patient needs.

SUGGESTED CODE OF ETHICS

- ✓ Always strive for the highest standards of excellence; never assume.
- ✓ Make sure that all devices are reprocessed as if they would be used on you or a family member.
- ✓ Practice competently. When in doubt, ask for advice from a qualified co-worker.
- ✓ Take responsibility for your work and make sure that it is completed on time and accurately.
- ✓ Developed by Nancy Chobin

MAJOR ETHICAL ISSUES

Entitlement
Ethic

Work Ethic

Ethical Issues
with Sales
Representatives

Ethical Issues
with Employees

Ethical Issues
with Patient
Safety

Ethical Issues
with Employees'
Safety

Entitlement Ethic

- Some people feel "**the world owes me.**"
- Might feel that the policies of an organization should not apply to them; they should be treated with special favors.
- Feel that they deserve more than what they have in life.
- Regardless of what they have, they always believe that they deserve more.
- Unfair to other staff members who abide by the rules.
- Can be a cause of dissent in the department.



Seem Familiar??????



“You ought to thank me for showing up for work today!”



Solutions

1

Treat all employees the same – no favoritism

2

Make sure explanations are clear and concise

3

Provide rationale for decisions

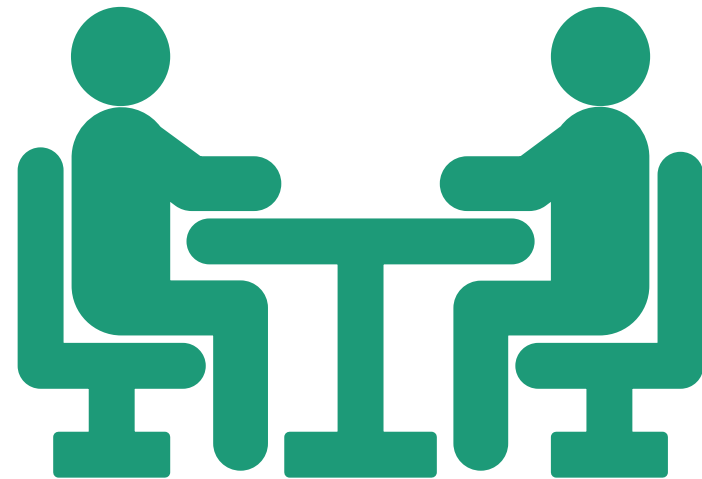
Work Ethic

- We work in a diverse environment
- People from different cultures need to work together
- Differences in cultural beliefs or behaviors create misunderstandings between staff members



Solutions

- Learn as much as possible about how cultural differences affect work practices.
- Incorporate the differences into departmental functions without compromising the processing aspects.
- Understanding the differences can facilitate teamwork that is needed for a well-functioning processing area.



Patient Confidentiality

- Processing technicians have access to confidential patient information through GI/Endo or operating room (OR) schedules, computerized records, the issuing of equipment, and charge systems.
- This information is highly confidential --should never be discussed with anyone at any time unless it is required for the direct care of the patient.
- All healthcare facilities must comply with the Health Insurance Portability and Accountability Act (HIPAA), which provides for the confidentiality and security of health information.
- Each facility should also have procedures regarding the destruction of confidential records.



Solutions

- Never provide any patient information unless it is required for the patient's care.
- Avoid discussions in public places i.e.; elevators, coffee shop, cafeteria
- **Penalties for civil violations (Office for Civil Rights of US HHS)**
- HIPAA violation: Unknowing Penalty range: \$100 - \$50,000 per violation, with an annual maximum of \$25,000 for repeat violations
- HIPAA violation: Reasonable Cause Penalty range: \$1,000 - \$50,000 per violation, with an annual maximum of \$100,000 for repeat violations
- HIPAA violation: Willful neglect but violation is corrected within the required time period Penalty range: \$10,000 - \$50,000 per violation, with an annual maximum of \$250,000 for repeat violations
- HIPAA violation: Willful neglect and is not corrected within required time period Penalty range: \$50,000 per violation, with an annual maximum of \$1.5 million

HIPAA Violations

- **Criminal penalties**

- Criminal violations of HIPAA are handled by the DOJ. Different levels of severity for criminal violations.
- Covered entities and specified individuals, who “knowingly obtain or disclose individually identifiable health information, in violation of the Administrative Simplification Regulations, face a fine of up to \$50,000, as well as imprisonment up to 1 year.
- Offenses committed under false pretenses allow penalties to be increased to a \$100,000 fine, with up to 5 years in prison.
- Finally, offenses committed with the intent to sell, transfer or use individually identifiable health information for commercial advantage, personal gain or malicious harm permit fines of \$250,000 and imprisonment up to 10 years.



FACILITY PROPERTY

Stealing or damaging department or facility property is an ethical issue.

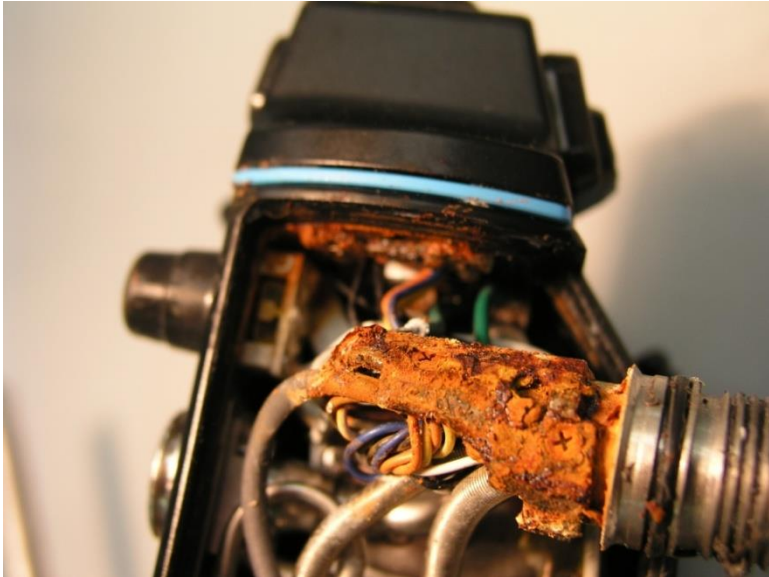
Equipment used in patient care is expensive and must be used as directed by the instructions.

Abuse of equipment is costly to the facility especially if the abuse is not noticed before the equipment is needed.

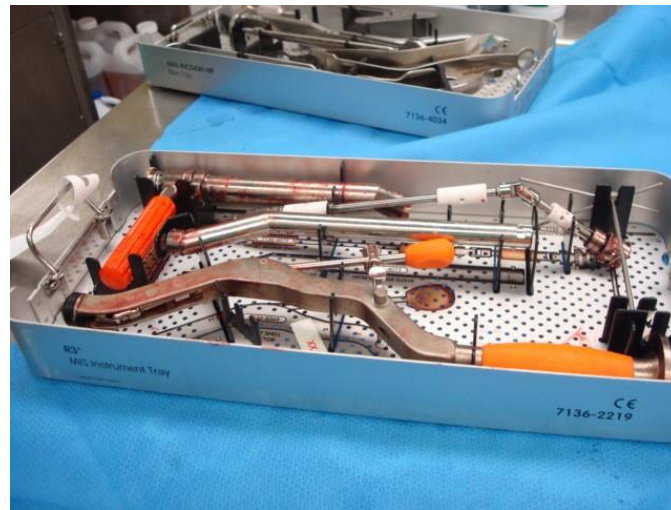
Sometimes when personnel witness such activity, they do not want to “get involved.”

Ethically, the right thing to do is to report it.

Preventable Damage to Equipment



- Endoscope damage due to failure to perform a leak test or perform it correctly (no time).
- Broken tip of scissors result of “dumping instruments” from basket onto workstation.
- Failure to perform POU treatment – corrodes instruments.



Solutions

- Ensure policies and procedures reflect current national standards
- Monitor staff compliance with policies
- Monitor the documentation for all critical processes – ensure it is accurate and complete



SALES REPRESENTATIVES

- The end user of any product or equipment has the responsibility to ensure it is used and processed according to the most current written instructions for use (IFUs) (FDA).
- **The FDA requires device manufacturers to provide end users with validated processes for cleaning, inspection, testing, packaging, HLD or sterilization of reusable devices.**
- **Sometimes, we get verbal information which may not be accurate.**
- Inaccurate or outdated IFUs can impact on patient safety.



Solutions

- Get the IFUs (best way)
 - From the company's home office - should have the most current IFU available
 - Computerized IFU service
- I always use the concept of “trust but verify”.
- Always ask for information in writing and keep it on file.
- IFUs must be readily accessible to staff; in the Decontam area and the HLD or Sterilization area.
- Ensure staff can select the correct IFU and speak to it when asked
- Keep them updated; date when update received



SALES REPRESENTATIVES

- Loaned instruments – why do we permit overweight sets?
- Why do we allow loaned instruments to arrive at any time?
- Is there a loaned instrument policy? Does it specify:
 - The maximum weight of sets
 - All instruments/container must be in good condition
 - Must arrive in (state specific time frame) to ensure processing per the IFU
 - Count sheet and current IFU provided?
- If not, WHY?????
- Ethically, we need to ensure a “standard of care” for EVERY patient.
- This is OUR problem!

EMPLOYEE BEHAVIOR

- Sometimes employees feel that they “do not want to get involved,”
- Don’t report problems (i.e., staff member leaving the workplace for several hours or not reporting for work at all (but gets paid because he/she “forgot” to punch in or punch out).
- Results in a financial loss to the facility and needs to be reported.
- Unfair to the employees who do not exhibit unacceptable behavior.



Ethical Issues in Processing

- Includes compliance with regulatory standards, best practices, procedures and/or guidelines that impact on patient, employee or environmental safety; reporting instances of non-compliance.
- Unethical professional behavior includes
 - Non-compliance with dress code
 - Disruptive behavior
 - Theft
 - Willful damage to equipment/property
 - Non-compliance with policies **

Ethical Issues

- Making changes to processes to satisfy scheduling needs.
- Not reporting breaches in process – fear of loss of employment and/or litigation.



Solutions – SPD and Endoscopy

- Do you perform audits to ensure compliance with
 - Pre-treatment at the point of use – performed and if so, performed correctly?
 - Transport of used instruments/scopes to decontamination room
 - Donning recommended PPE
 - Compliance with complete IFUs for reprocessing?
 - Leak testing/ testing leak tester for accuracy?
 - Manual cleaning – correct dilution of detergents? Using recommended cleaning brushes? If reusable, being reprocessed after each use?
 - Correct water temperature?
 - Recommended water quality for cleaning and rinsing?
 - HLD – either manual or AER

Solutions - Audits

- Testing the HLD solution before each use ?(if indicated)
- Drying scope channels using instrument air?
- Using recommended pressure?
- Transporting scopes to storage using clean gloves and protected from re-contamination?
- Storage cabinet kept clean/scopes tagged with date, initials of preparer and statement (e.g., HLD)
- Scopes transported to procedure room to protect from re-contamination?

EMPLOYEE SAFETY

- Need to report noncompliance with stated policies, e.g.,
- Not wearing PPE,
- Failure to adhere to all processing protocols,
- Other instances of noncompliance with policies and procedures.
- These issues relate to employee and patient safety and must be reported.

Employee Training - Endoscopy

- Endoscopy processing personnel need to be properly trained in the correct processing practices.
- Need to make sure they receive comprehensive training and oversight.
- Study in *American Journal of Infection Control* “Very few frontline endoscopy professionals receive formal training in proper endoscope reprocessing practices”.
- Survey involved 88 endoscopy technicians and nurses who were asked about their experience and knowledge of endoscope care and infection prevention practices.
- [AORN: https://www.aorn.org/outpatient-surgery/articles/enews-briefs/june-3-2021](https://www.aorn.org/outpatient-surgery/articles/enews-briefs/june-3-2021) - Survey Reveals Knowledge Gap in Endoscope Processing.

Employee Training - Endoscopy

- 90% of the endoscopy professionals surveyed expressed confidence in their abilities to reprocess endoscopes properly.
- The average score on a competency test of best practices in endoscope reprocessing given as part of the survey was **just 62%**.
- Many techs said they began reprocessing scopes independently **within a month of employment**, and most had not been certified to perform the task.
- There is no excuse for properly trained staff.
- [AORN: https://www.aorn.org/outpatient-surgery/articles/enews-briefs/june-3-2021 - Survey Reveals Knowledge Gap in Endoscope Processing.](https://www.aorn.org/outpatient-surgery/articles/enews-briefs/june-3-2021 - Survey Reveals Knowledge Gap in Endoscope Processing)

Lack of Trained and Competent Staff

- During Covid, many SPD staff left the profession and never came back
- Lack of candidates; poor candidates
- Accepting lesser candidates due to staffing needs
- Short staffing leads to taking short cuts in training
- Patient care can suffer as a result
- Can lead to staff burnout, surgeon/OR dissatisfaction, and poor patient outcome



Sterile Processing Training



- A survey of hospitals (1998) about various aspects of training sterile processing personnel, including the length of time for training employees to process general surgical and specialty surgical instruments was performed.
- Study repeated 10 years later.
- A majority of the 2008 respondents regarding training responded:
 - 60% training would take three to six months
 - 31% - training would take 6-12 months 52% said that most preceptors spend two to three months working with new employees.



Sterile Processing Training



- The cost to train a sterile processing technician to the competent level, including the salary of the preceptor, was \$41,414 for 2008, an increase of more than 100% from the 1998 calculation.
- These costs must be weighed against the loss of revenue when procedures are delayed because of missing, damaged, or unclean instruments and the patient safety issues that could result if an employee is not well trained.
- These costs are rarely referenced when trying to add staff or develop a comprehensive training program.

Sterile Processing Staff

- Recent study:
- Wide variation in training programs, certification backgrounds for SPD staff
- In most states, a standardized pathway to employment does not exist; training left up to the individual facility
- Employment requirements are variable, and certifications specific to this space do not correlate significantly with workplace roles or positions of leadership
- **There is little financial or career incentive to obtain formal training or additional certifications that may improve the quality of sterile processing.**
- Ethically, this needs to be addressed by every state, every facility.
- Why is this not happening? Does anyone care?

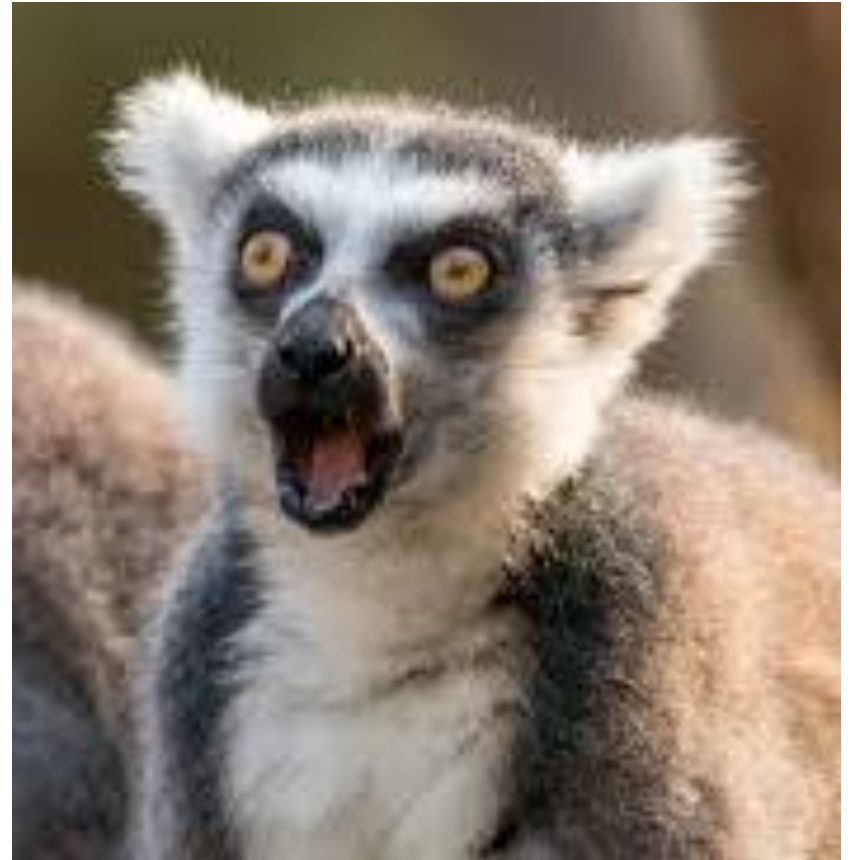
• "Do formal education or certification opportunities in sterile processing enhance career advancement"? Laura L. Bellaire , Meaghan Kenfield , Kevin Janek , Weston Balch , Justin Poulton , Lindsay Brown , Samuel Mosiman , Peter Nichol. Perioperative Care and Operating Room Management , June, 2023.

Push to Keep Busy











- Hospitals and surgery centers need to keep OR and procedure rooms fully scheduled to maximize the use of resources and patient throughput.
- Causes a ripple effect throughout the chain of support services
- Causes delays in available supplies, capital equipment and instruments to be ready and available when the patient and physician are scheduled for a procedure.
- When cases are booked back-to-back with insufficient equipment, the processing suffers.
- Short cuts are taken. Who will know????????????
- Article in the *American Journal of Infection Control*, "**Reprocessing failures can have dire consequences for patients, and infections have been associated with ureteroscopes, cystoscopes, bronchoscopes, colonoscopes, gastroscopes, and duodenoscopes**". (Cori Ofstead)
- Multiple lawsuits regarding improperly processed instruments.
- C.L. Ofstead et al. / *American Journal of Infection Control* (2019) 1–7, Accessed 12/12/2019 [www.ajicjournal.org/article/S0196-6553\(19\)30849-1/fulltext](http://www.ajicjournal.org/article/S0196-6553(19)30849-1/fulltext)

WHY DOES THIS CONTINUE?

- **Inadequate Device Cleaning IFU Makes Top 10 Health Tech Hazards List**
- **ECRI (Emergency Care Research Institute)**



The top 10 health technology hazards list at a glance

	1 Medical devices may pose usability challenges for home users , risking misuse and patient harm		6 Ransomware targeting the healthcare sector remains a critical threat
	2 Inadequate or onerous device cleaning instructions endanger patients		7 Increased burn risk with single-foil electro-surgical return electrodes
	3 Sterile drug compounding without the use of technological safeguards increases the risk of medication errors		8 Infusion pump damage remains a medication safety concern
	4 Overlooked environmental impacts of patient care endanger public health		9 Poor QC of implantable orthopedic products can lead to surgical delays and patient harm
	5 Insufficient governance of AI used in medical technologies risks inappropriate care decisions		10 Third-party web analytics software can compromise patient confidentiality

Source: ECRI, OR Business Management Conference. Used with permission.

Solutions

- Ethically, we must comply with all policies and IFUs.
- Conflict emerges when we are told to “hurry up” – fear of losing our job
- Why should you have to choose between your job and “doing the right thing?”
- **You shouldn't**

Incidents Being Reported About SPD

- A whistleblower claims sterile processing practices at XXXX Hospital of XXX, are out of compliance with federal and state regulations and create an immediate risk of danger and serious physical harm to its patients, according to written complaints she filed Sunday with multiple state and federal agencies.
- A former sterile processing manager at the facility claims in her complaints that she was fired after making several reports of unsafe working conditions and unsterile practices at the hospital.

Solutions

- There is a moral imperative for individuals and healthcare systems and providers to establish a culture of safety that involves every person in patient care (**Michael Brenner**, MD, FACS, associate professor, department of otolaryngology-head and neck surgery at the University of Michigan.);
 - Need to have every facility focus on safety
 - **Use only well-trained reprocessing staff.** “If you don’t have someone who pays meticulous attention to details in how they reprocess your instruments, it can absolutely lead to infections.” **Kerri Ubaldi**, RN, MBA, CPHRM, vice president of operations, Merritt Healthcare in Ridgefield, CT
 - If you are concerned about processes, **FIRST** inform your Manager, Infection Prevention, Risk Management and/or Human Resources.
 - You are obligated to bring such matters to the attention of Administration – they are most likely unaware of these issues.
-
- Reprocessing and Cleaning Breaches Haunt Some Ors. <https://www.reliasmedia.com/articles/144712-reprocessing-and-cleaning-breaches-haunt-some-ors>



Finances

- As practitioners, we are obligated to “first, do no harm”.
- It is unacceptable to not have adequate
 - Staffing
 - Equipment
 - Supplies/Instruments
- Who determines what is adequate?
- Does the surgeon or endoscopist have any idea how long it takes to process a flexible endoscope or instruments for a spinal case?
- Do you?
- The average scope takes 76 minutes to process correctly. The average trauma set can take up to 75 minutes per tray.

Seem Familiar?



Time to Process a Flexible Endoscope

Table 3: Staff time and wages paid to complete basic reprocessing activities for one endoscope

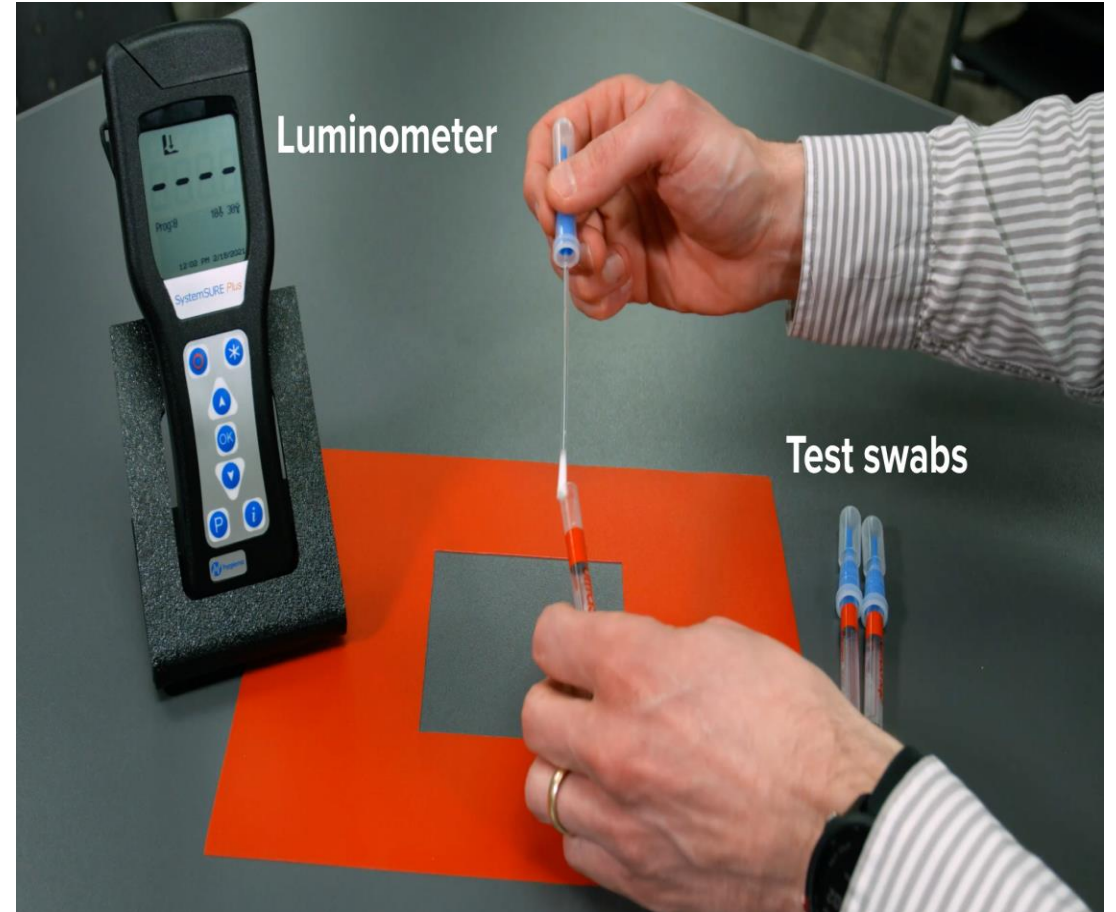
Reprocessing step	Average time required* (minutes)	Cost of staff time for reprocessing tasks**		
		CS Tech \$16.80/hr	Surgical Tech \$22.09/hr	RN \$34.14/hr
PPE changes and hand hygiene [†]	9.1	\$2.54	\$3.34	\$5.16
Bedside pre-cleaning	5.8	\$1.61	\$2.12	\$3.27
Transport to reprocessing room	5.5	\$1.54	\$2.02	\$3.13
Dry leak testing	2.1	\$0.59	\$0.77	\$1.19
Wet leak testing	5.5	\$1.54	\$2.02	\$3.13
Manual cleaning	17.3	\$4.85	\$6.38	\$9.86
Sinks and counter clean-up	6.0	\$1.68	\$2.21	\$3.41
Visual inspection	3.0	\$0.84	\$1.10	\$1.71
Performing cleaning verification tests	5.4	\$1.52	\$1.99	\$3.08
Re-cleaning & re-testing [‡]	4.5	\$1.26	\$1.66	\$2.56
Setting up AER [§]	4.0	\$1.12	\$1.47	\$2.28
Drying endoscope & accessories	7.3	\$2.03	\$2.67	\$4.13
Transport to storage	0.5	\$0.15	\$0.20	\$0.31
Total time and wages for reprocessing one endoscope	76 minutes	\$21.27	\$27.95	\$43.22

*Time estimates provided by CS and endoscopy center staff from several institutions; **Average wages obtained from the United States Bureau of Labor Statistics. †Time for donning/doffing PPE includes two complete changes of PPE, donning gloves two more times, and performing hand hygiene twice.

‡Assumes 20% of endoscopes require re-cleaning due to results of visual inspection and cleaning verification tests. §Time for setting up AER includes loading endoscope, connecting channels, entering data, testing MEC, removing endoscope, and documentation. It does not include time for running the cycle.

Cleaning Effective Testing

- **All critical scopes** should be tested each use after cleaning (AAMI ST-91)
- Other scopes should be tested per facility policy (establish schedule)
- Ethically every scope should be tested so there is a standard of care for all patients
- Why would you HLD or sterilize a scope if it isn't clean?



High-Risk Endoscopes

- Includes
 - Duodenoscopes
 - linear ultrasound (EUS) endoscopes
 - bronchoscopes
 - endobronchial ultrasound (EBUS) endoscopes
 - ureteroscopes and
 - cystoscopes



Visual Inspection



- AORN, AAMI and SGNA all state that visual inspection of scopes should be performed before HLD or sterilization.
- Visual inspection, followed by enhanced visual inspection (e.g.; with a lighted magnification (5-10x)
- What about arthroscopic shavers and other lumened devices?
- For internal channels, a borescope can be used.
- Are you compliant?



— Where Are We Now?

- The AAMI documents are still not widely known or in use in HCFs
- People still working in “Silos”
- They hate change so they continue to do things “like we always did”
- Number of legal actions for improperly processed instruments and endoscopes continues to rise (I have consulted on 15 so far)
- Why does a facility wait for a lawsuit to do something?

REPORTING

- Each facility has a corporate compliance policy; some facilities have a hot-line that can be used to anonymously report any compliance issues.



REMEMBER



- Ethics means doing the right thing.
- When processing surgical instruments, devices and endoscopes, attention to detail and the ability to do the right thing is required....all the time, not just when we have the time.
- This means taking a long, hard look at our practices.
- Management is responsible to oversee processing,

FALSIFICATION -

- You cannot rationalize non-compliance with a stated policy or IFU.
- Documents that are falsified can lead to immediate termination of employment.
- Falsified documents can lead to criminal prosecution.
- Falsification of documentation of CEUs can lead to revocation of your license and/or certification!



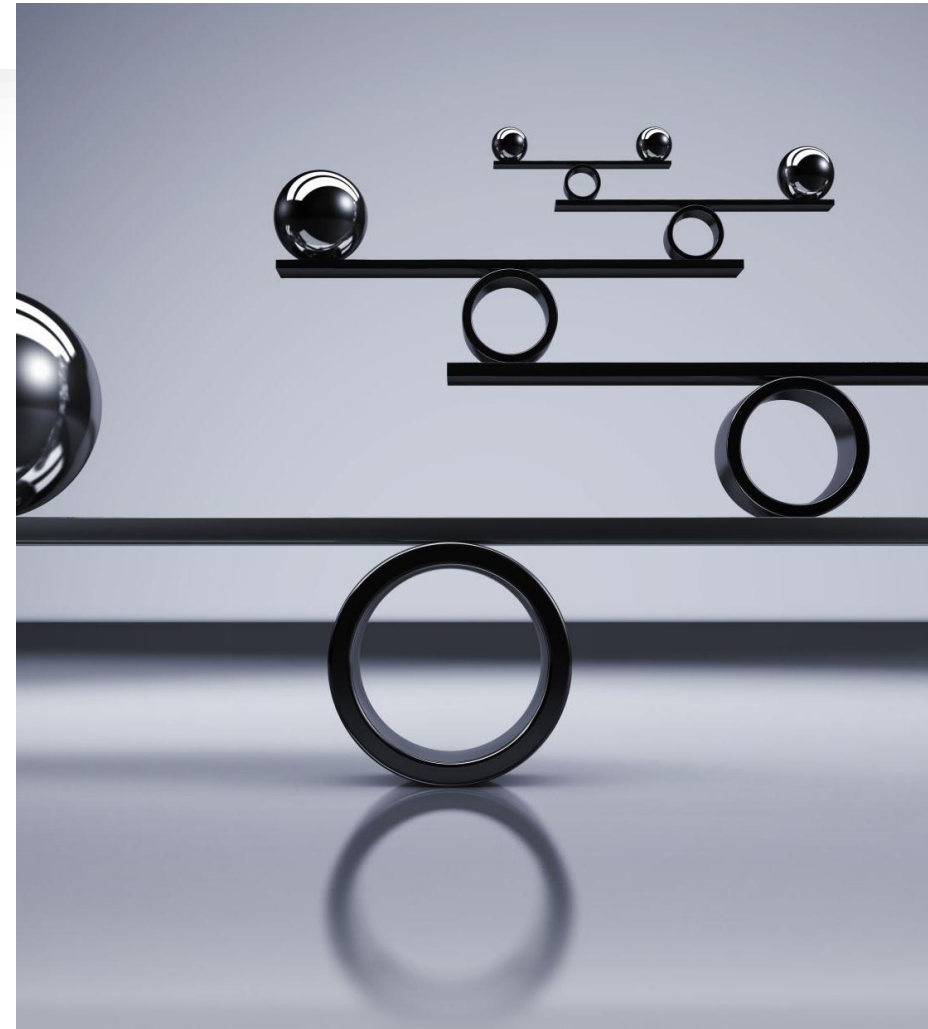
IMPORTANT REMINDERS



- Is staff thoroughly trained with competencies verified initially and annually?
- Who performs the competencies?
- Do you have a sufficient inventory of instruments, scopes, processing equipment and staffing to permit processing in full compliance with the IFUs?
- Is there a quality monitoring system in effect to monitor compliance with IFUs and verify the cleaning of devices and scopes before high-level disinfection or sterilization?

DEALING WITH ETHICAL ISSUES

- Cannot rationalize out of ethical dilemmas.
- Solutions not always black or white.
- Action must be an informed decision based upon sound professional skills and knowledge
- **Fear of losing your job/educating others should not dictate or influence your stand.**

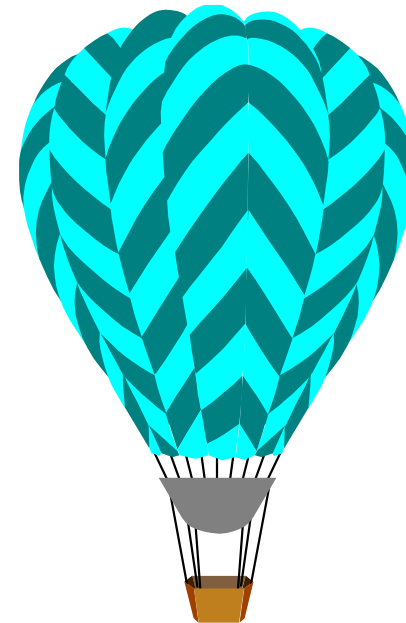


**SOMETIMES YOU JUST
NEED A NEW
PERSPECTIVE
ON THINGS!**



The End

- As we drift along with the changes in healthcare, we need to reaffirm our personal and professional ethics.
- We selected to work in healthcare, our patients are counting on us.



THANK YOU!!!!



Contact: nancy@spdceus.com.

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