Special Problems Associated with Reprocessing Instruments in Outpatient Care Facilities

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Disclosure

Consultant for Cogentix Medical

Objectives

- **Statistics on Outpatient Care in the US**
- **Three Main Problems with Instrument Reprocessing in Out Patient Care:**
  - **3. Physical Space Problems**
    - Improvements achieved without renovation
  - **2. Training and Education Problems Related to High-level Disinfection**
    - IFUs/Validation
    - Industry standardization
    - HLD Education
  - **1. Lack of Infection Prevention Presence**

UNC HOSPITALS

Outpatient Care in the US

More patients obtain healthcare in specialty clinics and physicians' offices in the United States than in hospitals.

- 990 million ambulatory care visits to US physician offices (most specialties)
  - 85% of all adults in the US had contact with a health care professional in the past year
  - 93% of children in the US had contact with a health care professional in the past year
- 126 million outpatient hospital visits (CDC 2011)

CDC: 2015 https://www.cdc.gov/nchs/fastats/physician-visits.htm

UNC HOSPITALS

Under-reporting of Transmission Associated with Endoscopy

In a CDC survey, 1/3 of respondents reported that their institutions have not used any surveillance methods to identify possible bacterial transmission following certain endoscopic procedures.

Beekmann, S.E., Palmore, T.N., Polgreen, P.M, Bennett, J.E. (2016). Adequacy of Duodenoscope Reprocessing Methods as Reported by Infectious Disease Physicians. Infect Control Hosp Epidemiol, 37(2), 226-8.

Sterilization
Enormous Margin of Safety!

100 quadrillion (10^{-17}) margin of safety

Sterilization kills 1 trillion spores *in addition to* the washer/disinfector which removes or inactivates 10-100 million microbes.

There is a 1:100 quadrillion chance of the item NOT being sterile.

Rutala

Generally speaking, and particularly compared to HLD, I don't worry about steam sterilization practices.

High-Level Disinfection
No Margin of Safety for GI Endoscopes

0 (zero) margin of safety;

Microbial contamination 10^7-10^{10}: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

<u>Maximum contamination, minimal cleaning</u> (10^2)/HLD (10^4)

Rutala

I do worry

about high-level disinfection practices.

In fact…

High-level disinfection

is

the problem with instrument reprocessing today – inpatient and outpatient.

Special Problem #3:
Physical Plant Challenges

(or, One Reason Our Outpatient Areas Need Infection Prevention)

Double Sinks: Both clean or both dirty.

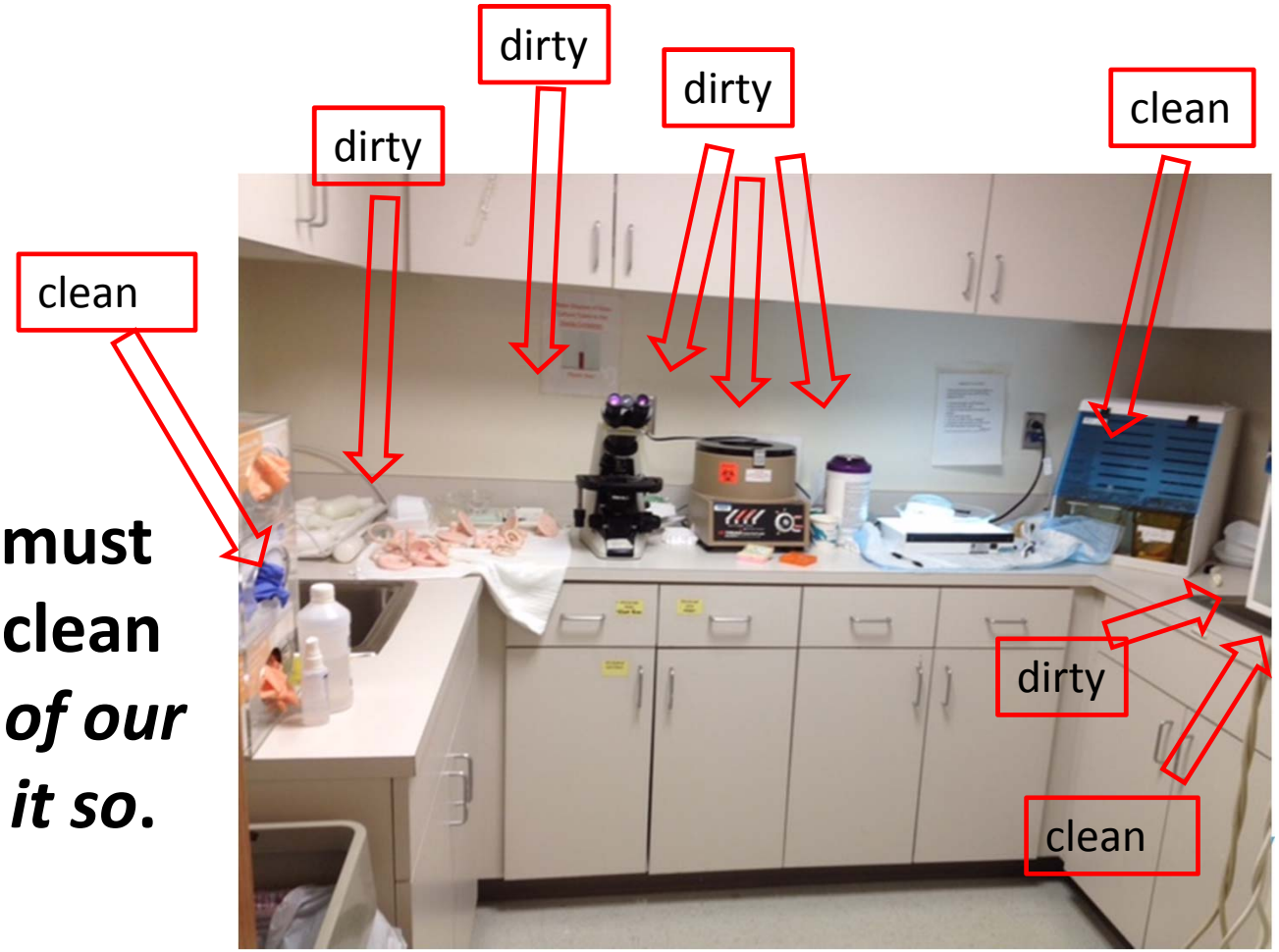
We helped them figure this out.

- No sink at all
- Storage of endocavitary probes in processing room

We made it safer.

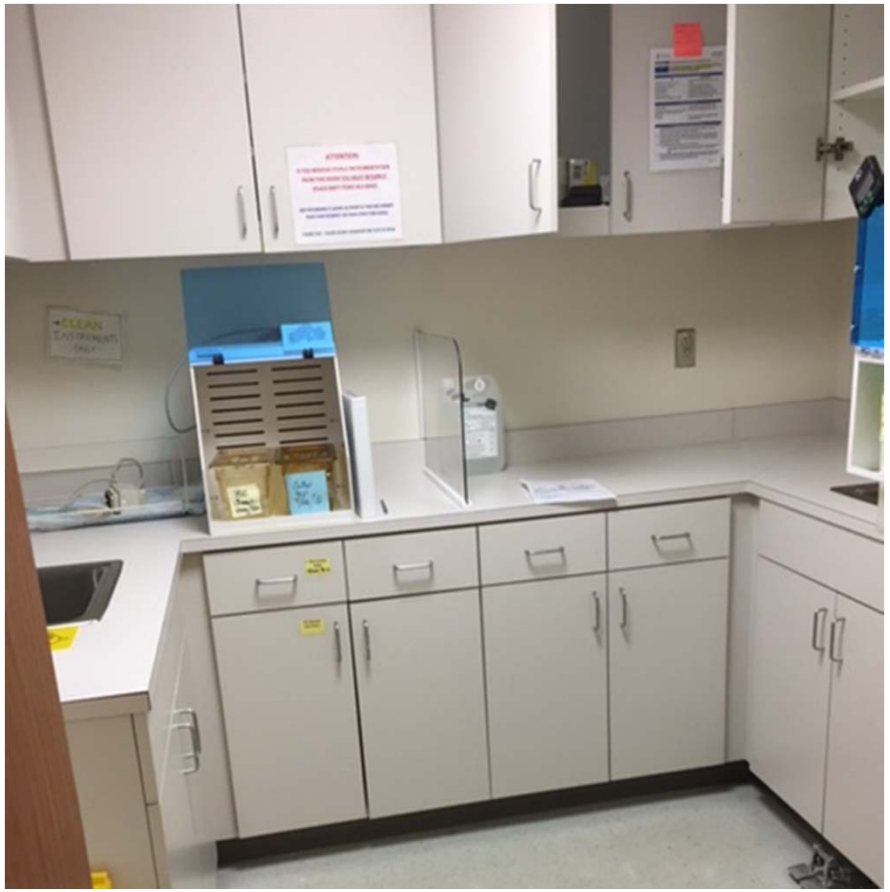
Before Infection Prevention Assistance…

This is a “clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean” set up.



Critical: rooms must have a dirty-to-clean flow *to the best of our ability to make it so*.

After Infection Prevention Assistance – it's all rainbows and unicorns!



They decluttered and established a "dirty-to-clean" flow (mostly).

We helped them figure this out.

Special Problem(s) #2: Training, Education, Validation and Standardization

(or, 4 reasons our outpatient areas need Infection Prevention)

Table of Contents for Olympus Q180V

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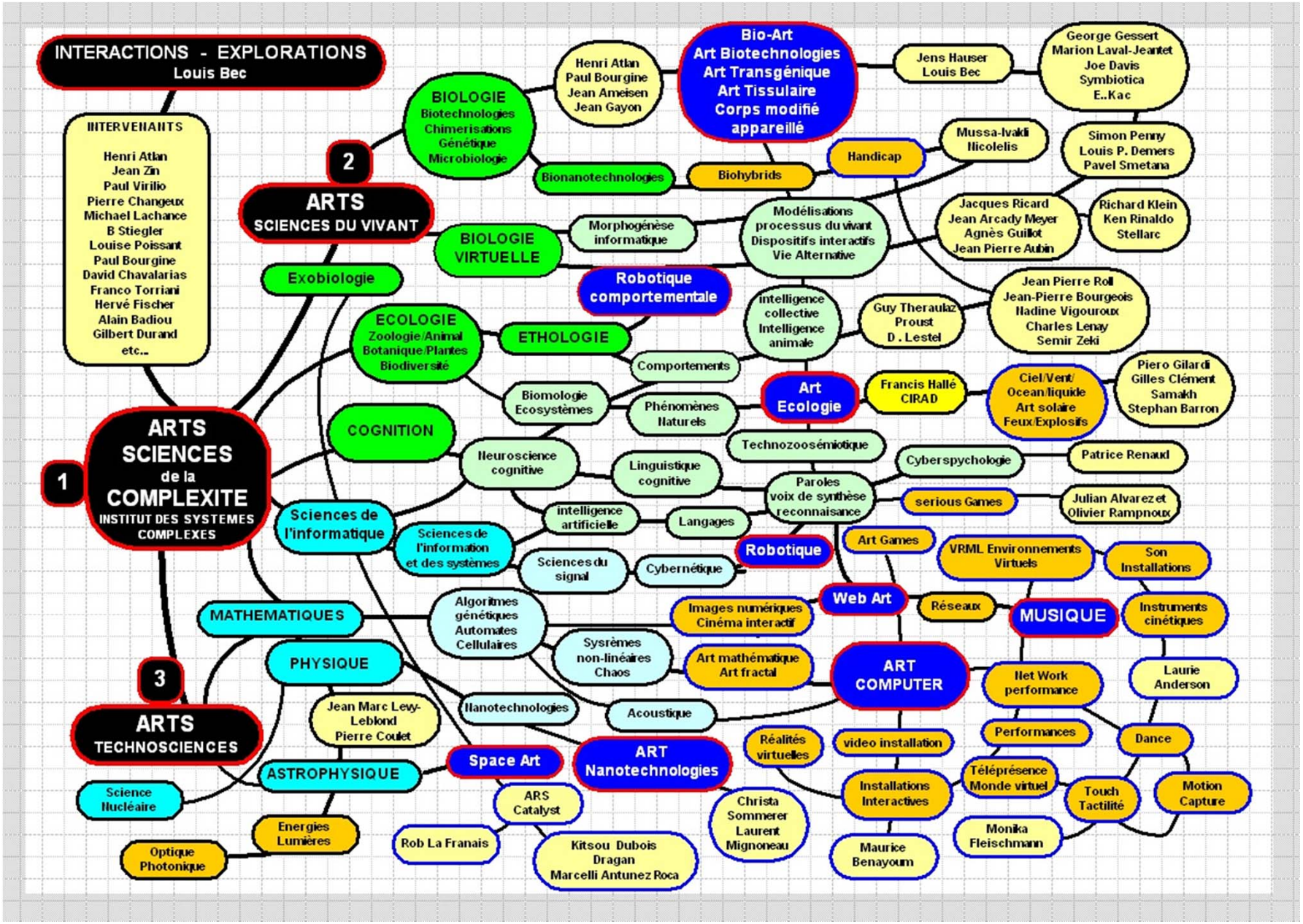
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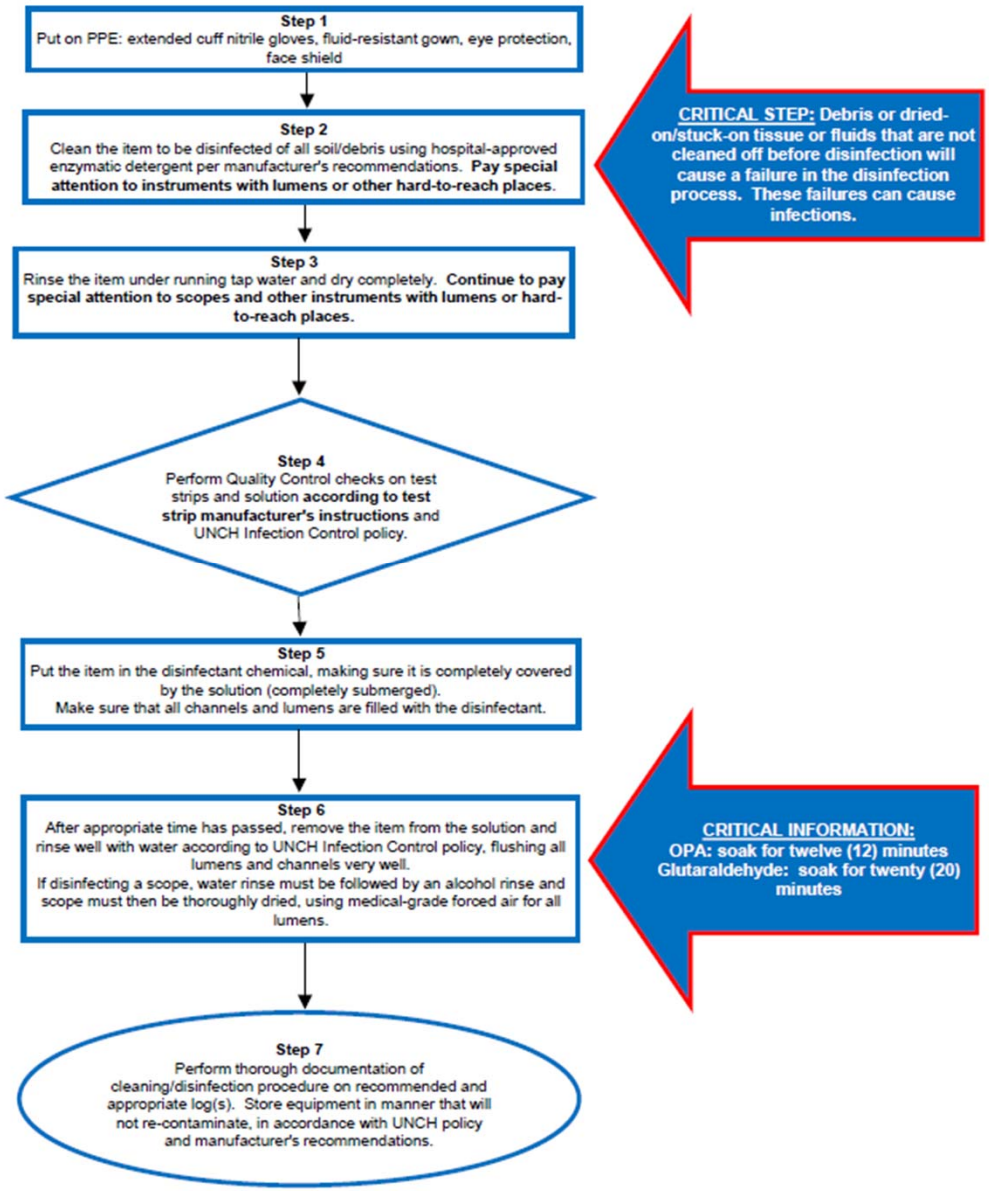
Kitsou Dubois
Dragan
Marcelli Antunez Roca
Maurice Benayoum
Energies Lumières
Optique Photonique

University of North Carolina Healthcare

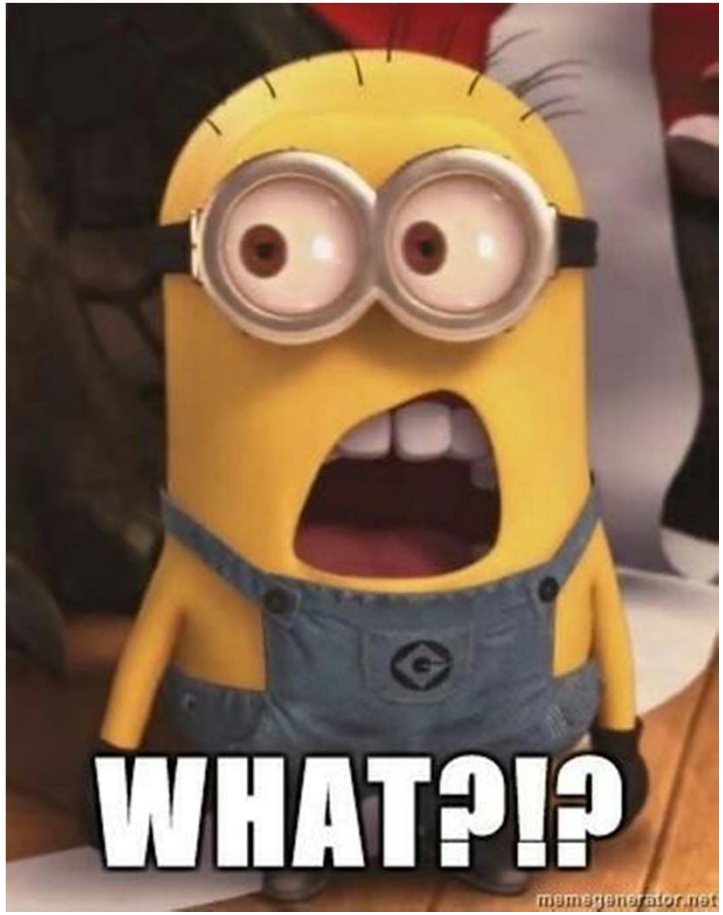
This is a document adopted by UNC Healthcare for its use in infection prevention.

Steps for High Level Disinfection of Equipment Using Glutaraldehyde or OPA



UNC Healthcare Hospital Epidemiology
rev 0315

The UNCH HLD Workshop has educated over 500 staff in 5 years.



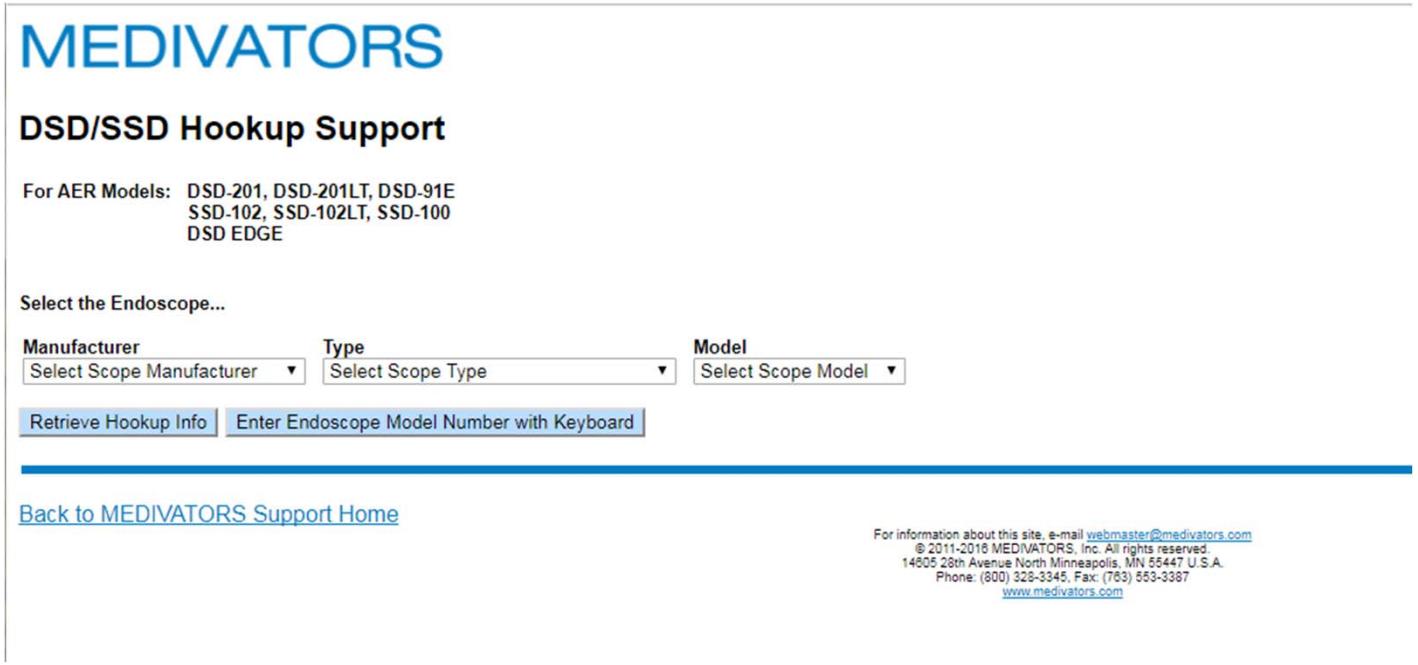
Computer-based training does not work for HLD!

The VALUE in Validation…

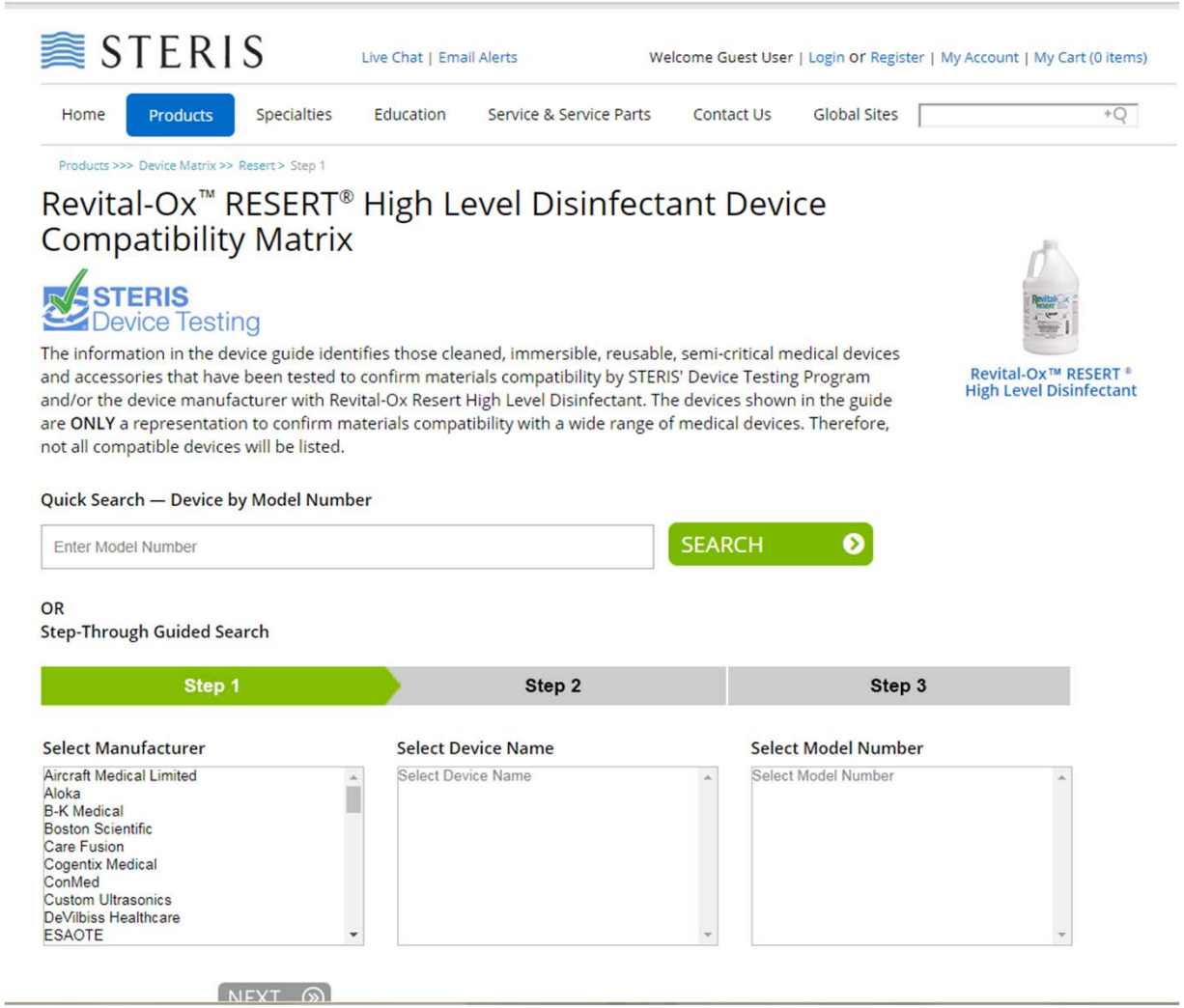
Device Validation

- Are HLD chemicals validated by device manufacturer?
- Is the device validated by the manufacturer of the automated endoscope reprocessor (AER)?
- Does the device have lumens?
- Is the sterilizer or AER validated to be efficacious with those lumens?
  - Length, diameter play a role
  - Are here hookups or adapters that must be used to perfuse lumens?
  - Are the correct hookups in use?

Device/Hook-up Validation



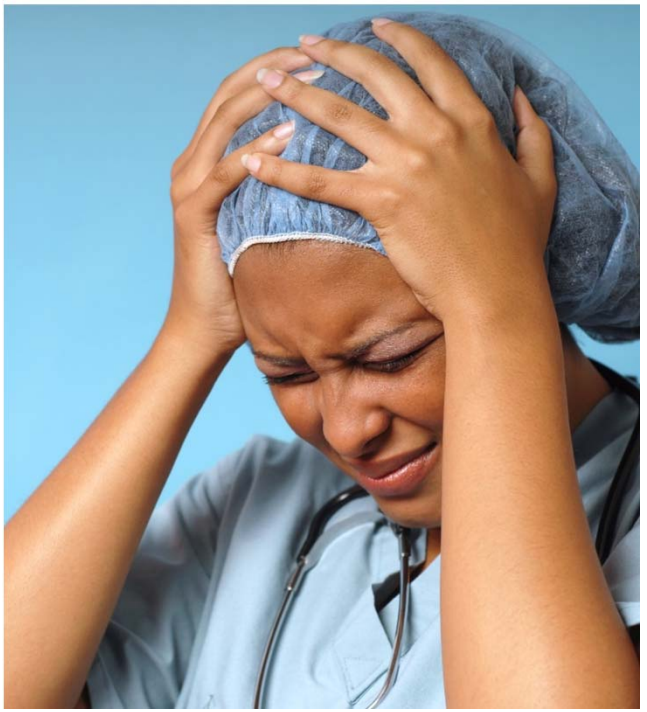
Chemical Validation



No Standardization in the Instrument Reprocessing Industry

Enzymatic Detergents - No Standardization

- Different ratios of detergent to H_2O
- Automated dispensing systems
  - Are they REALLY accurate?
  - Are we checking accuracy?
- Some require certain H_2O temperatures for efficacy
- All must be precisely measured
- All require specific and different soak times
- None are disinfectants – a risk to staff!!



A Plethora of Detergents and Cleaners

Instrument Stain Remover

Manuf / Supplier: Medline

Compare

View Item List

Surgical Instruments High Suds Detergents

Manuf / Supplier: Medline

Compare

View Item List

Cart Washer Detergent

Manuf / Supplier: Medline

Compare

View Item List

Alkaline Detergent

Manuf / Supplier: Medline

Compare

View Item List

Enzyme Super Concentrate Surgical Instrument Detergent

Manuf / Supplier: Medline

Compare

View Item List

Prolystica™ Enzymatic Presoak and Cleaner by Steris

Manuf / Supplier: Steris Corp

Compare

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Enzol Enzymatic Instrument Cleaner by Johnson & Johnson

Manuf / Supplier: Johnson & Johnson

Compare

View Item List

Prepzyme X. F. eXtreme Foam by Ruhof

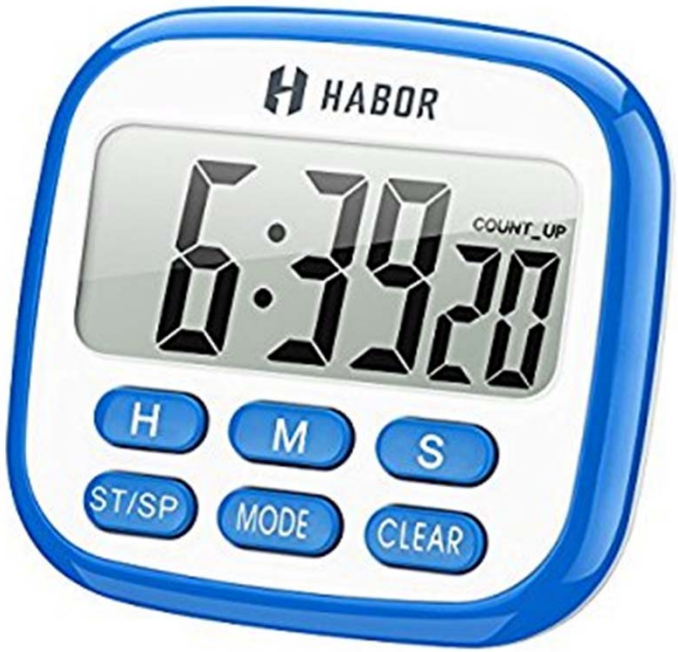
Manuf / Supplier: Ruhof Healthcare

Compare

View Item List

HLD Soak Times and Usage: No Standardization

- Most glutaraldehyde is a 20 minute soak time (unheated)
- Revital-ox Resert® is an 8 minute soak time
- OPA is a 12 minute soak time
- Rapicide® HLD glutaraldehyde is only FDA approved to be used heated in an automated endoscope reprocessor (AER)



Test Strips: No Standardization

- Staff may not leave the instrument processing room during wait times
  - 3M Comply™ glutaraldehyde strips
    - 5 minutes – shades of yellow
  - Cidex® glutaraldehyde strips
    - 75 seconds – pass = purple, fail = orange
  - Cidex® OPA strips
    - 90 seconds – pass = purple, fail = teal
  - Revital-Ox® strips
    - 60 seconds – pass dark blue, fail = mottled
  - Rapicide® PA strips
    - 30 seconds – pass black, fail = shades of gray/black

Special Problem #1:

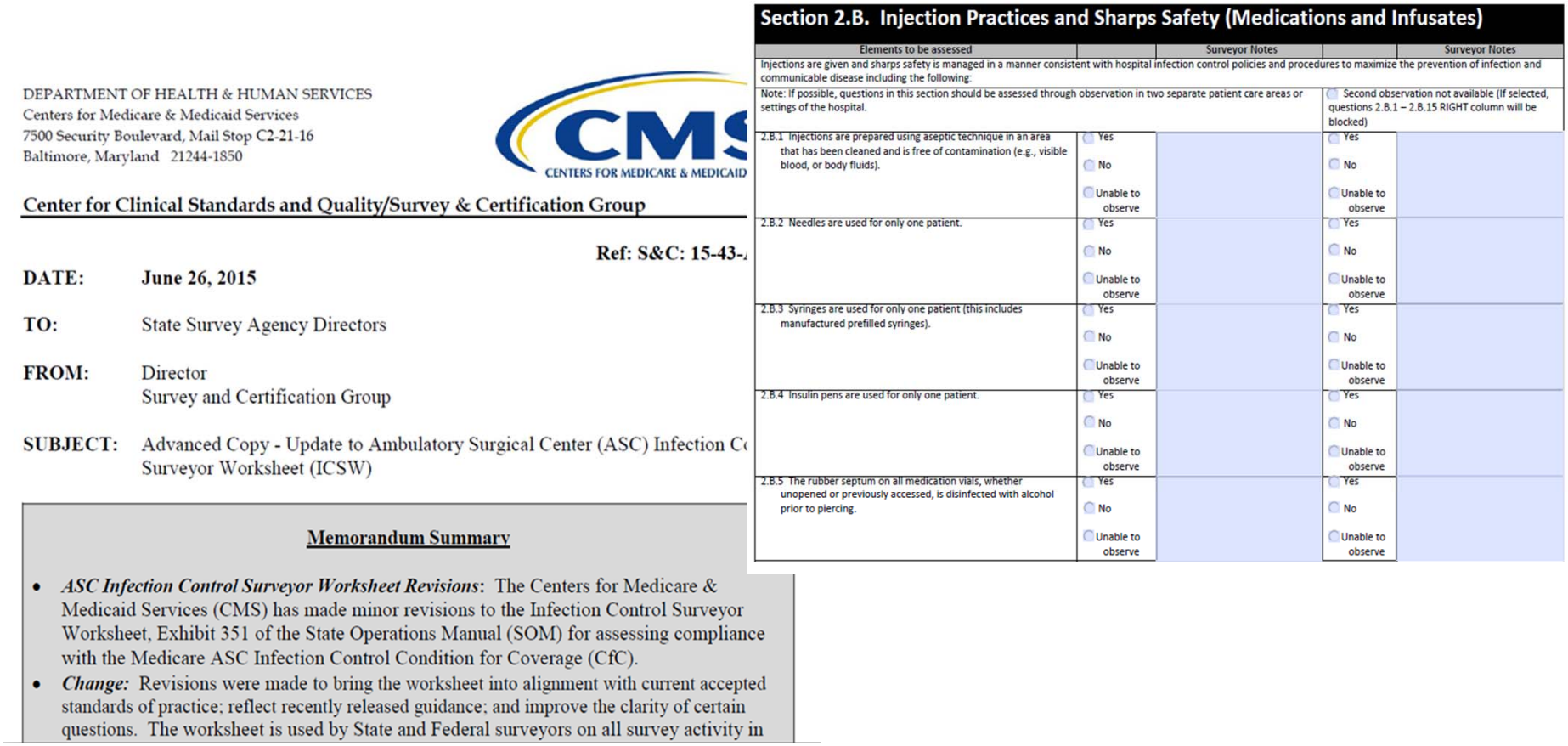
Lack of Infection Prevention Presence

But before we go…

Educate ourselves and become familiar with the process

CMS: Infection Control Worksheet

Two multi-page documents specifically for inspecting infection prevention practices in acute care and ambulatory surgical facilities.



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-

DATE: **June 26, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection C
Surveyor Worksheet (ICSW)

Memorandum Summary

- ***ASC Infection Control Surveyor Worksheet Revisions***: The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- ***Change:*** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in

Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)

Elements to be assessed		Surveyor Notes		Surveyor Notes
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:				
Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.			☐ Second observation not available (If selected, questions 2.B.1 – 2.B.15 RIGHT column will be blocked)	
2.B.1 Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
2.B.2 Needles are used for only one patient.	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
2.B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes).	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
2.B.4 Insulin pens are used for only one patient.	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
2.B.5 The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol prior to piercing.	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

High-Level Disinfection (HLD) and Sterilization BoosterPak

June, 2017

GIE

SPECIAL ARTICLE

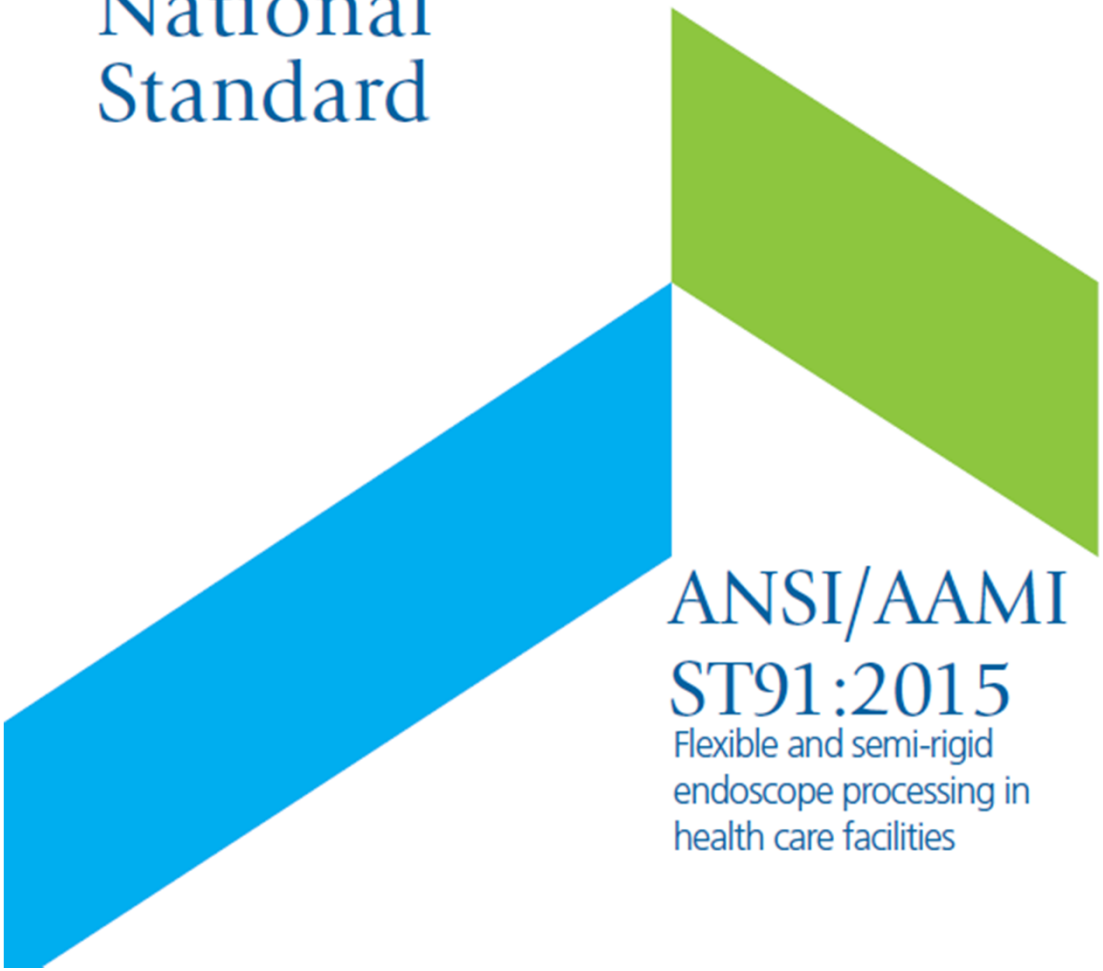
Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

American National Standard



ANSI/AAMI ST91:2015

Flexible and semi-rigid endoscope processing in health care facilities

Sept and Oct, 2015 Regulatory Recommendations: Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official

CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
October 2, 2015, 08:00 EST (08:00 AM EST)
CDCHAN-00383

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

As a follow-up to HAN 00382 (distributed September 11, 2015), the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are providing this update to rescind the following recommendation: If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services. We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Summary

On September 11, 2015, CDC issued HAN 00382 alerting healthcare providers and facilities about the

- Incomplete immersion
- OPA in a cystoscopy clinic
- They did not know…

We helped them figure this out.

Storage Challenges

We helped them figure this out.

Separation Strategies

Clearly distinguishing between clean and dirty items.

What's dirty and what's clean?

We helped them figure this out.

What did we do? We helped them figure this out.

Inadequate Space

Yep – here too!

This is OUR watch and we cannot do nothing.

Don’t let what you cannot do interfere with what you can do.

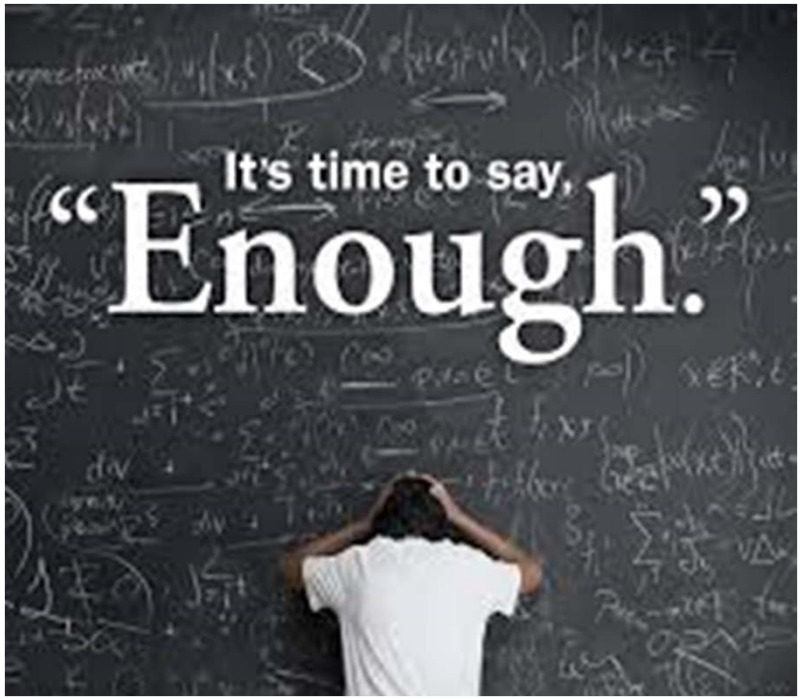
- There has never been a time in which we must partner with industry like we must partner today
- Infection Prevention must be engaged at a level not seen before

Thousands of known human infections (and thousands more unknown) are associated with failures in HLD – either human or engineering.

Infection Preventionists are responsible for giving solvable issues our attention immediately.

Industry is responsible for immediately creating engineering controls on devices that make it difficult to infect a patient…such as single use, sterile devices and sheaths.

We are responsible for continuing the pressure on industry to do so.



Our First Step after today
(like, on Monday)

Step One…

Tuck *ANY* HLD Guideline under your arm

and

walk into

your scope processing room,

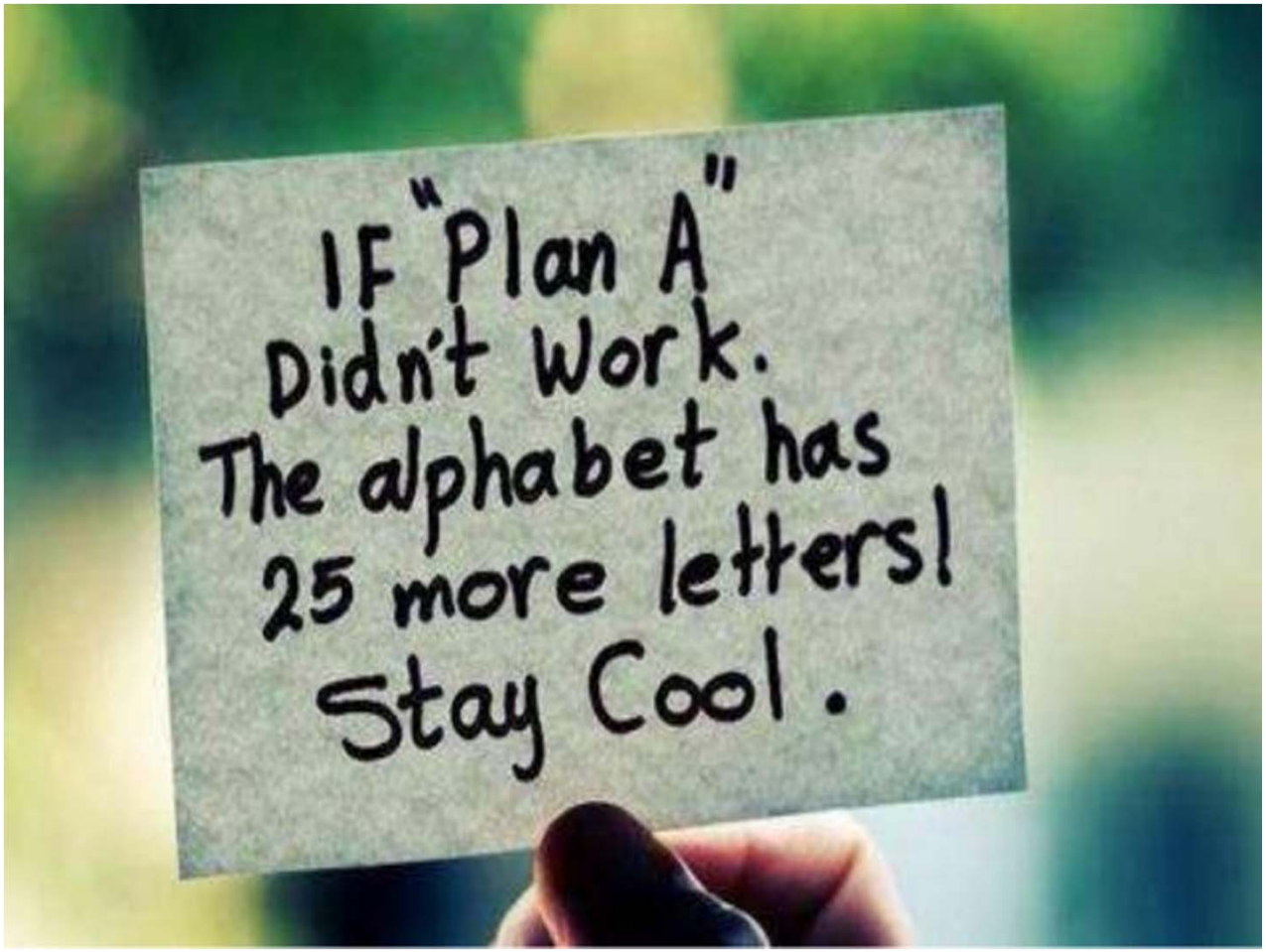
your instrument processing

room, your instrument

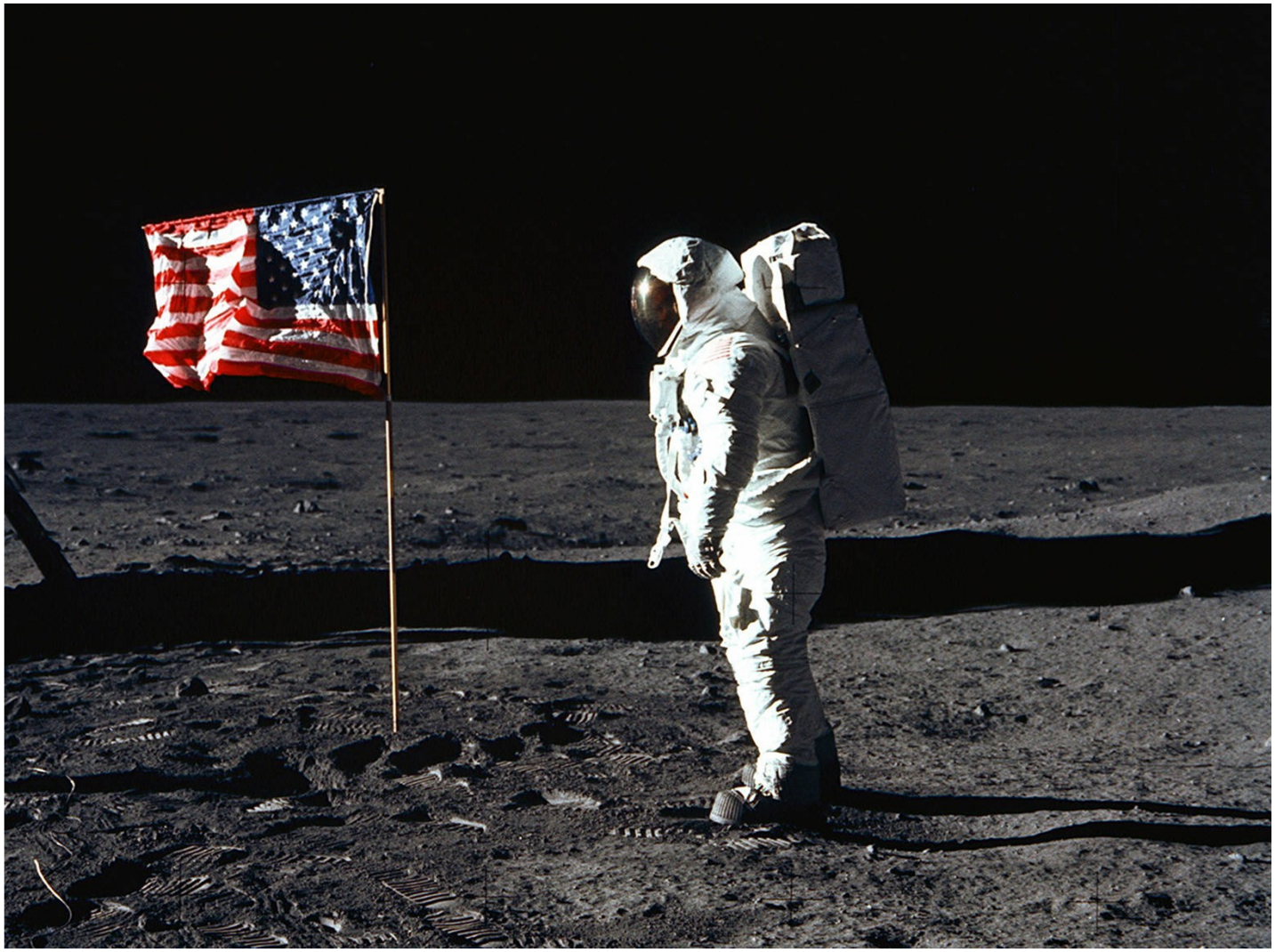
processing closet and start a

conversation.

- IT WAS A MISTAKE for me to ASSUME people who HLD ***everyday*** know the right way to do it.
- Your instrument reprocessing sites need your attention and help.
  - They may not know that yet.
- We *CANNOT* always make it perfect or even consistent with regulations and guidelines.
- We *CAN* always make it better and safer for our patients and our staffs. I personally guarantee that.
- Just start your first visit…the rest will happen for you automatically.
- Fix the worst things first.


IF "Plan A"
Didn't Work.
The alphabet has
25 more letters!
Stay Cool.

Once we, *Infection Prevention,* is fully engaged, the myriad elements and complexities of HLD within our facilities will lead us where they need us to go –



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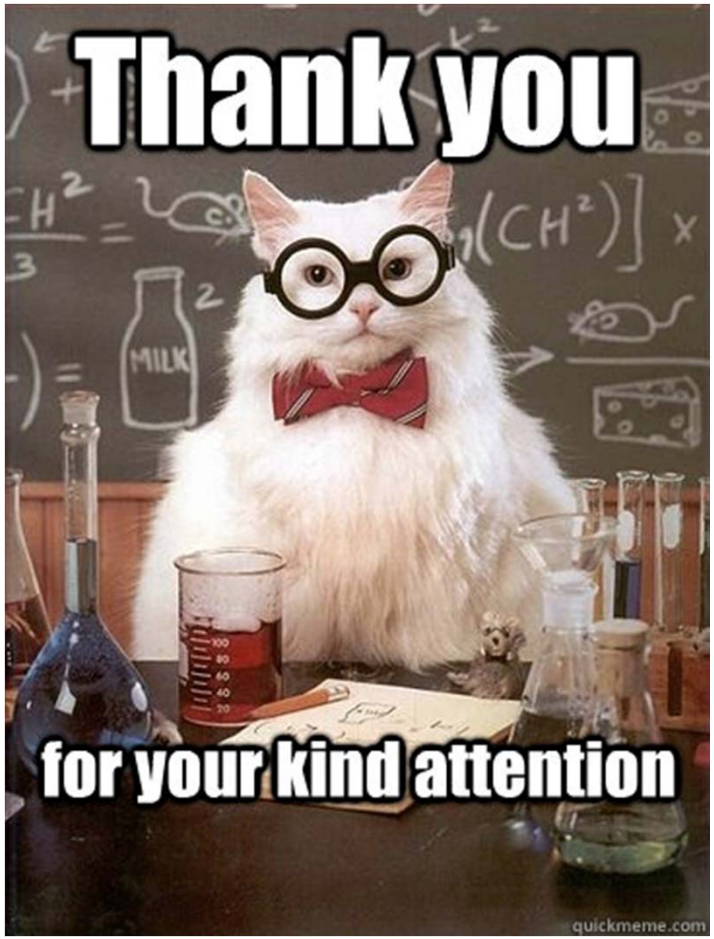

Thank you to Drs. Rutala, Weber, and Sickbert-Bennett and the entire staff of UNC Hospital Epidemiology. Without every one of my colleagues in Chapel Hill, this presentation would not be possible. They have given me all the opportunities I asked for (and some I didn't).

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