Dealing With Manufacturers' Instructions for Use

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Objectives

- Know the importance of IFUs and manufacturer's instructions for instrument reprocessing.
- Understand how critical thinking and objective evidence can contribute to best practices and acquisition of best products.
- Understand why validation has become an FDA requirement for medical device manufacturers.
- Know how information you receive from vendors needs to be reviewed and instructions may need to be reconciled with practice requirements.

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Background

- Sophistication of medical/surgical procedures has resulted in new generation of instruments and medical devices.
- Devices vary in size, weight, complexity, immersibility.
- Vary in cleaning, disinfecting and sterilization processes.

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Regulatory Requirements

- FDA enforces AAMI documents including TIR-12: (Manufacturer's IFU standard).
- FDA requires MDMs to validate their product label claims of reusability and provide complete and comprehensive written instructions for:
  - Pre-treatment, cleaning, disinfection, inspection, maintenance, testing, packaging, sterilization, drying and aeration (if applicable).
- Users must verify MDM instructions in their facility utilizing their own equipment and resources.

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Manufacturers Instructions for Use

- IFUs may include information about maximum number of times the item may be reprocessed as well as storage requirements.
- It is important to understand that each patient care item has its own IFUs for cleaning and disinfection and the expectation is that the organization will follow those instructions.
  - Failure to follow such instructions or misuse creates significant risk to safe, quality care.

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The Joint Commission

- Standard IC.02.02.01 requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies.
  - This standard is applicable to Joint Commission-accredited hospitals (HAP), critical access hospitals (CAH), ambulatory (AHC) and office-based surgery (OBS) facilities.

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The Joint Commission

- The most vulnerable locations for lapses in sterilization or HLD of equipment are:
- Ambulatory care sites (including office-based surgery facilities) and
- Decentralized locations in hospitals, even though the data shows higher noncompliance rates for critical access hospitals and hospitals.

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New JC Requirements for Infection Prevention

- Effective July 1, 2024 - new and revised requirements for the "Infection Prevention and Control" (IC) chapter for critical access hospitals and hospitals.
- The IC chapter had a full rewrite to specify
- The facility's infection prevention and control program has
- written policies and procedures to guide its activities and
- methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings.

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New JC Requirements for Infection Prevention

- EP 4. The policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:
- Cleaning, disinfection, and sterilization of reusable medical and surgical devices in accordance with the Spaulding classification system and manufacturers' instructions.

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New JC Requirements for Infection Prevention

- Required documentation for device reprocessing cycles
  - sterilizer cycle logs,
  - frequency of chemical and biological testing, and
  - the results of testing for appropriate concentration for chemicals used in high-level disinfection
- Resolution of conflicts or discrepancies between a medical device manufacturer's instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment

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Consequences

- The consequences of failed processes may result in serious outcomes for the organization. These include:
- Placing patients at risk for contamination
- Causing potential outbreaks
- Potential loss of Joint Commission accreditation
- Potential loss of Centers for Medicare and Medicaid Services (CMS) deeming status
- Bad publicity, lost business and a damaged reputation
- Litigation

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Deficiencies

- Users cannot follow the instructions from just one manufacturer if similarly functioning devices are being used from multiple manufacturers.
- Each manufacturer's instructions must be followed specifically for the particular device.
- This means that there can be different cleaning, disinfection, and sterilization processes for the same type of device but made by different manufacturers.

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Deficiencies

- During the past five years, findings related to cleaning, disinfection, and sterilization have been among the top five drivers of Joint Commission Immediate Threat to Health or Safety (ITHS) declarations. I
- Not only are deficiencies pertaining to medical device reprocessing among the most frequently cited, but they also are among the most immediately hazardous.

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Training

- For especially challenging devices with complicated cleaning protocols:
  - Multi-part devices, devices with narrow lumens, powered equipment
  - Provide training materials (e.g. videos/manuals) to enhance personnel education
  - Provide competency verification initially and annually
- The device manufacturer should consult with manufacturers of cleaning products and equipment to develop cleaning instructions

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Understanding Requirements

- Manufacturers' compliance with AAMI standards is voluntary.
- Not legally obligated to comply unless they claim to do so (most do).
- Manufacturers are required to report to the FDA:
  - Any medical device-related patient injuries or deaths
  - Malfunctions that could cause injury/death

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Liability and Patient Safety

- Without IFUs, the device may not be cleaned, packaged, disinfected or sterilized correctly.
- Can result in processing failure – inexcusable.
- Facility assumes full responsibility for the safety and efficacy of the device.
- Using a product off-label.

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Sterilization Instructions

- Manufacturers are required to provide users with IFUs which may include:
  - Listing of 510ks
  - Claims like:
    - Shelf-life vs event related dating
    - Lumens
    - Internal and external stacking
    - Compatibility with current sterilization modalities
  - Reprocessing instructions
  - Useful life of product (reusable? Reposable?)

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Cleaning Instructions

- Manufacturers of devices intended for reuse should provide to the user, in writing, specific information regarding:
  - Type and necessary quality of the water (e.g., distilled water, deionized water, water treated by reverse osmosis, filtered water, or hard or softened tap water)
  - Type and quality of cleaning agents and cleaning accessories that should be used
  - Handling and preparation of devices for cleaning
  - Manual or mechanical method that should be used for cleaning, rinsing, and drying

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Validation of Cleaning Process

- To assure users that an item can be successfully decontaminated, device manufacturers should develop and provide:
  - Decontamination recommendations that provide for thorough cleaning and meet clinical markers.
  - Can be performed in the healthcare facility using commonly available chemicals, supplies, and equipment.
  - Can be duplicated by healthcare personnel.

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Manual Cleaning

1. Rinse in cold water (<109° F) to remove visible debris and to prevent coagulation of blood.

2. If applicable, disassemble the instrument into its component parts.

3. Ensure that suction levers or stopcocks are in the full open position or disassembled.

4. **Soak for a minimum of 10 minutes in enzymatic detergent and DEIONIZED water.**
Dilute the enzyme according to the instructions for use

5. Remove soil from challenging design features with cleaning brushes to:

a. Scrub the surface with a scrub brush.

Note: To access the surfaces of flexible devices, gently bend the instrument by pushing it against the side of the cleaning tub with one hand, making sure not to damage the device.
Bend at several locations along the length of the device to access all crevices.

b. Scrub interfaces, cannulations, holes and all crevices of the flexible portions of the instrument with tight-fitting cleaning brushes using a twisting motion to remove additional soil.

c. Scrub crevices and around hinged/mated surfaces with a brush.

6. Rinse thoroughly with warm water. While rinsing, use a clean brush to irrigate the cannulations, holes and all crevices.
To do so, move the brush back and forth through the cannulations, holes and all crevices SEVERAL TIMES.

7. **Sonicate for a minimum of 15 minutes in an ultrasonic cleaner with enzymatic detergent and DEIONIZED water.**

8. Rinse thoroughly with warm deionized water making sure to irrigate any lumens and/or crevices.

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Validation of Cleaning Process

- Procedure should be easily understood by the user.
  - E.g. diagrams and step-by-step instructions are helpful to personnel.
  - Are in alignment with the recommendations of professional organizations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens (29 CFR 1910.1030).
  - Include a method by which users can verify effective decontamination.

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Validation of Cleaning Process

- MDM must use scientifically valid methods and show that the recommended cleaning process is effective in removing the simulated soil from all surfaces of the device that could come in contact with:
  - Patient
  - Accessible to tissue
  - Blood
  - Body fluids
  - Other organic materials

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Design Considerations

- When designing devices, small, narrow openings should be avoided
  - Can provide sites for corrosion
  - Can harbor microorganisms
  - How can they be cleaned?
  - Do they need to be flushed?
  - Is your sterilizer validated for the internal diameter of the lumen?
  - Is your sterilization container (regular or IUSS) validated for the length and/or internal diameter of the any lumened devices?

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How Accurate Are Your IFUs?

- Some are confusing
- Some are too brief
- Some are too detailed
- Some can be wrong and misleading

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Healthcare Personnel

- Responsible to make sure that the cleaning methods recommended **can be duplicated in their environment**.
- Ensure all instructions followed correctly.
- May require training by device manufacturer
  - On-site preferred
  - Hands-on
  - Return demonstration
  - Competency verification

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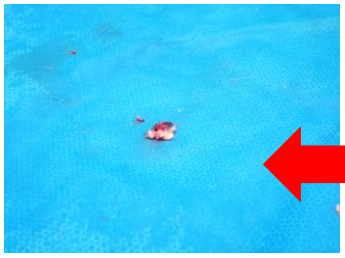
When IFUs are not Explained Or FOLLOWED…..



This is the result

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Reconciling

- How to reconcile manufacturer's recommendations and IFUs with good common sense?

- Let's see some examples.

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EXAMPLE 1: XXX Spine Instruments IFU

- Clean microsurgical instruments separate from routine instruments
- Disassemble devices which can be disassembled
  - **If the device has a sliding mechanism or hinged joints, clean all areas where fluids can accumulate**
  - Clean all cannulated instruments using a brush of appropriate diameter and length to clean all interior surfaces of cannula
  - Rinse thoroughly
- Use a neutral pH enzymatic detergent to soak instruments. Use a soft brush to remove any tissue or blood. Rinse
- Place all levels in ultrasonic cleaner and process for **10 minutes**
- **Place all levels of set in washer/decontaminator**

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XXX Spinal Instruments IFU con't

- **Steam sterilize as follows:**
- **Pre-vacuum steam sterilize**
- **TEMP. 270ºF – 275ºF (132º -135ºC)**
- **TIME: 6 minutes exposure**

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What's Wrong with XXX Spinal IFU

- IFU does **not** tell us **what** to disassemble or **how**!
- States to process all levels in a sonic and washer – does not clarify if all the levels of the container should be separated (per AAMI).
- Gives a range of sterilization temperatures.
- In the US we can only use 250ºF gravity for 30 minutes; 270º pre-vac for 4 minutes or 275º for 3 minutes pre-vac.
- Does not specify to clean each level separately
- We cannot use 272, 273, 274 as they are not validated for use in the US. IFU does not specify this.

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Example 2: XXX Clamp IFU

- Remove Instrument Clamp from Vertical Bar.
- Remove Vertical Bar from Table Clamp.
- Immerse the XXX clamp System in ***soap.***
- Sterilize using moist heat.

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Example 2: XXX Clamp – Revised IFU

- Remove Instrument Clamp from Vertical Bar
- Remove Vertical Bar from Table Clamp
- Immerse the Fast clamp System in a detergent based water solution and leave to soak for a minimum of 5 minutes
- Use a soft brush to dislodge any tissue or blood
- Do not use automated cleaning
- Sterilize using moist heat
- **Minimum sterilization parameters** = 121 deg C @ 2 bar for **15 minutes using Gravity Displacement** with 10minutes minimum dry time.

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What is Wrong with Revised IFU for Clamp?

- This was the revised IFU received after company was informed they would be reported to the FDA.
- Still unacceptable--sterilization cycle does not meet AAMI minimum standards.
  - It does state **minimum** standards, however they can confuse processing technician that all they need is 15 minutes exposure at 250°F gravity displacement.
  - Could never dry a heavy table retractor with minimum 10 minutes dry time.

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Example 3: XXX SPINE INSTRUMENTS

- Cleaning Instructions for Complex Instruments that cannot be disassembled:
- Rinse/flush device and internal components with an Enzymatic cleaner
- Actuate device
- Scrub device for 3 minutes with soft bristle brush
- Soak in cleaner for 30 minutes in fresh cleaner
- **Shake device for 30 minutes on mechanical shaker at 250 osc/minute**

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XXX SPINE INSTRUMENTS con't

- Transfer to fresh cleaner and scrub for 3 minutes
- Flush internal components with syringe while actuating device for 1 minute
- Rinse with fresh DI water three separate times
- **Sonicate device in fresh enzymatic cleaner for 30 minutes**
- Scrub device for 3 minutes with soft bristle brush
- Flush internal components with syringe while actuating device for 1 minute
- Rinse with fresh DI water three separate times
- Achieved a 3.38 Log Reduction

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XXX Spine Explanation

- Soak in cleaner for 30 minutes in fresh cleaner
  - (What does this mean????)
- Shake device for 30 minutes on mechanical shaker at 250 osc/minute
  - **Turns out this is a paint mixer machine – Do you have one in your department?**

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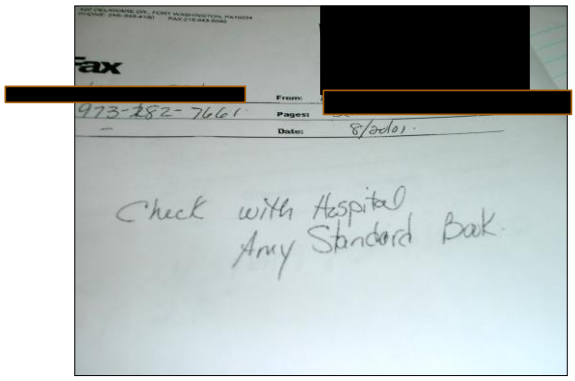
This Will Help?????



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Drying

- Minimum vs REQUIRED
- Some manufacturers now recommending dry times of 55-70 minutes for specialty sets!

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Extended Cycles

- Some manufactures have validated for extended cycles.
- No BIs or CIs currently on market validated for extended cycles.
- Most packaging materials have not been validated for extended cycles.
- Never place items in an extended cycle unless recommended.
- Ties up sterilizer for single item (can get small sterilizer for these cycles).

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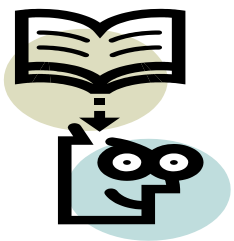
Extended Cycles

- Devices validated for “usual” cycle may be damaged in extended cycles – don’t assume you can place other items in an extended cycle.
- Barrier characteristics of packaging materials (and container filters) may be adversely affected.
- Check with packaging manufacturer for extended cycle validation.
- Get all the information in writing.
- Don’t assume.



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Why are IFUs Not Followed by SPD?

- IFU are not available/current
- IFUs not readily accessible where needed
- IFU are not easy to follow.
- The equipment and tools to follow them are not available in SPD.
- Not enough time/insufficient staffing to follow all the steps.

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Practice Problem Areas – Cleaning

- Taking short cuts in cleaning
  - Manufacturer recommends 20 minutes of sonication – Staff gives 5 min – Who will know?
  - Manufacturer recommends 20 minutes of soaking in an enzyme – Staff soaks 2 minutes – Who will know?
  - Washing multi-level sets with all levels inside container.
- Not reading the IFUs .
  - Assuming device gets cleaned “as usual”.
  - Traceability of the item/set to the staff member who performed the cleaning

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REALLY????

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Problem Areas – Cleaning

- Not having sufficient/proper processing equipment to comply with IFUs.
  - Should have one sonic for each washer – may need more if lots of extended cleaning protocols.
- OR does not send instruments to SPD immediately at the end of surgery.
  - One manufacturer recommends that cleaning be initiated no later than 30 minutes after use of the retractor.
  - Some MDMs now recommending cleaning be implemented immediately after use.
  - How can SPD comply without the cooperation of the end user?

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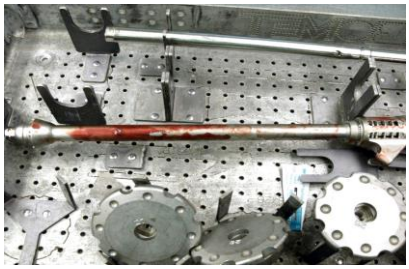
AORN Guideline for Instrument Cleaning 2024

- If blood is left on instruments for more than 20 minutes, the instrument will be marked and stained, especially if the blood is allowed to dry



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Problem Areas – Cleaning

- Staff not trained/educated in all instruments/devices.
  - Who did the training? How much time?
    - Attend inservice if provided by the sales rep.
    - Ask for their IFUs to follow along – see if they comply with their company's IFUs.
  - Was the device actually used?
  - Was a return demonstration required?
  - Was a competency assessment performed?
- Are reference materials readily available?

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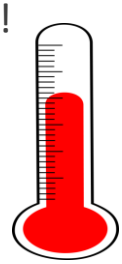
Problem Areas – Sterilization

- Not verifying manufacturer's IFUs for cycle type (gravity or pre-vac) and exposure time.
- Most facilities have MULTIPLE different cycles in use.
- One transducer is validated for 60 minutes at 270°F pre-vac!
- What happens when your staff gets an IFU with a temperature of 273° or 274°F?



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Problem Areas – Sterilization

- If you have sterilizers that operate at 270°F., what does staff do when the IFU gives a temperature of 275°F. and visa versa?
- What about: sterilize pre-vacuum steam at 270-280°F. for 3 minutes?
- What about drying?
  - If IFU says minimum of 8 minutes – do you use it?
- Are you checking – we have about 10% of Orthopedic or Neuro spine sets that require 50-70 minutes dry time!

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Steam Sterilization Cycles

- The sterilizer manufacturer's written IFU for cycle parameters should be followed.
- Programmed cycle selections should be used.
- Any differences between the programmed cycle parameters and the cycle parameters recommended by the medical device manufacturer should be investigated and resolved before the items are sterilized.
- Procedures for correct cycle selection should be developed and implemented, and process audits should be conducted to ensure compliance.

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Cycle Selection

- Must comply with the sterilizer manufacturer's IFUs for available cycles.
- You can adjust the exposure time as long as it does not fall below the minimum time for the set temperature (i.e., 4 minutes at 270 deg. F.)
- You cannot change the temperature to a temperature not validated by the sterilizer manufacturer (i.e. to 273, 274°F.)

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Cycle Type	Load	Sterilize Temperature	Sterilize Time	Dry Time	Prevac		Gravity	
					Default	Optional	Default	Optional
Gravity*	Full Load Fabric Packs	270°F	25 min	15 min		X		X
Gravity*	Full Load Fabric Packs	250°F	30 min	15 min		X	X	
Gravity*	Full Load Instrument Trays	270°F	15 min	30 min		X	X	
Gravity*	Full Load Instrument Trays	250°F	30 min	30 min		X		X
Liquid*	Three 1000ml Bottles	250°F	45 min	N/A		X		X
Prevac*	Single Fabric Pack	270°F	4 min	5 min		X	N/A	N/A
Prevac*	Full Load Instrument Trays	270°F	4 min	20 min	X		N/A	N/A
Prevac*	Full Load Instrument Trays	275°F	3 min	16 min	X		N/A	N/A
Flash**	Unwrapped, Non-porous Instrument Tray	270°F	3 min	1 min	X		X	
Express**	Single-wrapped Instrument Tray	270°F	4 min	3 min	X		N/A	N/A
Flash	Unwrapped, Non-porous Instrument Tray	270°F	10 min	1 min	X		X	
DART*	Bowie-Dick Test Pack	270°F	3½ min	1 min	X		N/A	N/A
Leak* Test	None	N/A	N/A	N/A	X		N/A	N/A

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Validation

- Some sterilizer manufacturers state you should only use the validated cycles listed in their User Manual.
- Other's state "If different cycle parameters (sterilize time and dry time only) other than those provided are required, it is the responsibility of the health care facility to validate the cycle.
- The FDA does not permit users to validate, we can only verify.
- Are you willing to assume liability for this?

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It IS SPD's Responsibility

- Don't rely on sales reps to get information for you.
- Obtain from the company's home office - most current information.
- Verify ALL information
  - If unclear, cycles not accurate, etc.
- Don't accept verbal information.
- Ask questions.
- Get information in writing.
- Date IFUs when received/update routinely. (every 2 years – yearly for loaned instruments).

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Obtaining IFUs

- Some facilities contract with on-line company for IFUs.
- There is a disclaimer that the information may not be current.
- Does the company review the IFU for compliance with AAMI minimum sterilization cycles?
- Staff needs to know how to access system (JC).
- Information must be accessible to user (i.e., Decontam, Prep, sterilization areas).

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Obtaining IFUs

- What happens when the system is down or there is a power outage?
- Are there hard copies for the devices processed?
  - JC cited a NJ facility for both of the above.
- What if the company has a general IFU (i.e. for Synthes sets), who confirms with the company that the specific set being processed fits into those IFUs?

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How to Comply

- Get the IFUs.
- Manual system – start with Orthopedic/Spinal vendors (most challenging).
- Then get other IFUs by service.
- Ask for them in pdf. – easy to keep on file.
- Copy and place in binder; one for Decontam, one for prep/sterilization area.

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How to Comply

- Ask staff to ensure IFU available for each item being processed, if not available, Manager should contact company to obtain them.
- Computer service – just having them on a computer does **not** meet the standard.
- Management needs to review them for accuracy.

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How to Comply

- Is staff checking the book/computer?
- How do you monitor staff compliance?
- Is the info posted, so staff can see it?
- Who reviews the IFUs for accuracy, safety, compatibility with approved cycles?
- Don't depend on staff to "find and read".
- Provide in-services, perform competencies with return demonstrations for sophisticated/complicated IFUs.

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How to Comply

- Make videos of the in-services as reminders.
  - For new employees
  - For staff members who infrequently process the device (e.g. overnight shift personnel)
  - Ask for videos from the company
- Visit the company's website – many have in-services on their webpage that can downloaded or accessed on-line
- Ask the company for reference charts.

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Summary

- Check the sources of information.
  - IFUs should be validated based on reliable, reproducible data and based on guidelines by official bodies.
- IFUs should be clear and current
- Taking shortcuts from IFUs can lead to serious problems.

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Summary

- It is up to SPD to use validated best practices, review the information provided, question and think critically about unproven claims or info that simply makes no sense.
- Infection prevention and patient safety is in our hands.

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QUESTIONS????????

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To Report Problems/Issues

http://www.fda.gov/Safety/MedWatch/default.htm

References:

- **AAMI –*Comprehensive Guide to Steam Sterilization & Sterility Assurance in HCF, 2017.***
- ***AAMI TIR 12* -Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2010, 2013, 2018**
- ***Basics of Sterile Processing, 7edition, 2019.***

The Joint Commission Guide to Reprocessing Reusable Medical Devices . Edited by Sylvia Garcia-Houchins, MBA, RN, CIC, and Russell N. Olmsted, MPH, CIC, FAPIC. 2023

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