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# Strategies to Inform Device Reprocessing Policy Toward Patient Safety

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June 13,2022

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# Learning Objectives

| | |
|---|---|
| Describe | Describe the importance of device reprocessing policy and compliance with federal and national standards and guidelines for patient and staff safety. |
| Recognize | Recognize challenges infection preventionists can face when identifying standards and guidelines to inform device reprocessing policy. |
| Discuss | Discuss guidance, strategies and solutions for developing policies, based on practical experience from an expert in regulatory and accreditation standards. |
| Explain | Explain the role of AAMI and ANSI in the development of American National Standards, recognition by the FDA and how standards can inform policy and practice across a facility. |

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# Resolving Conflicts Between MIFUs, Standards and Guidelines

Daniel Lightfoot, Ph.D.

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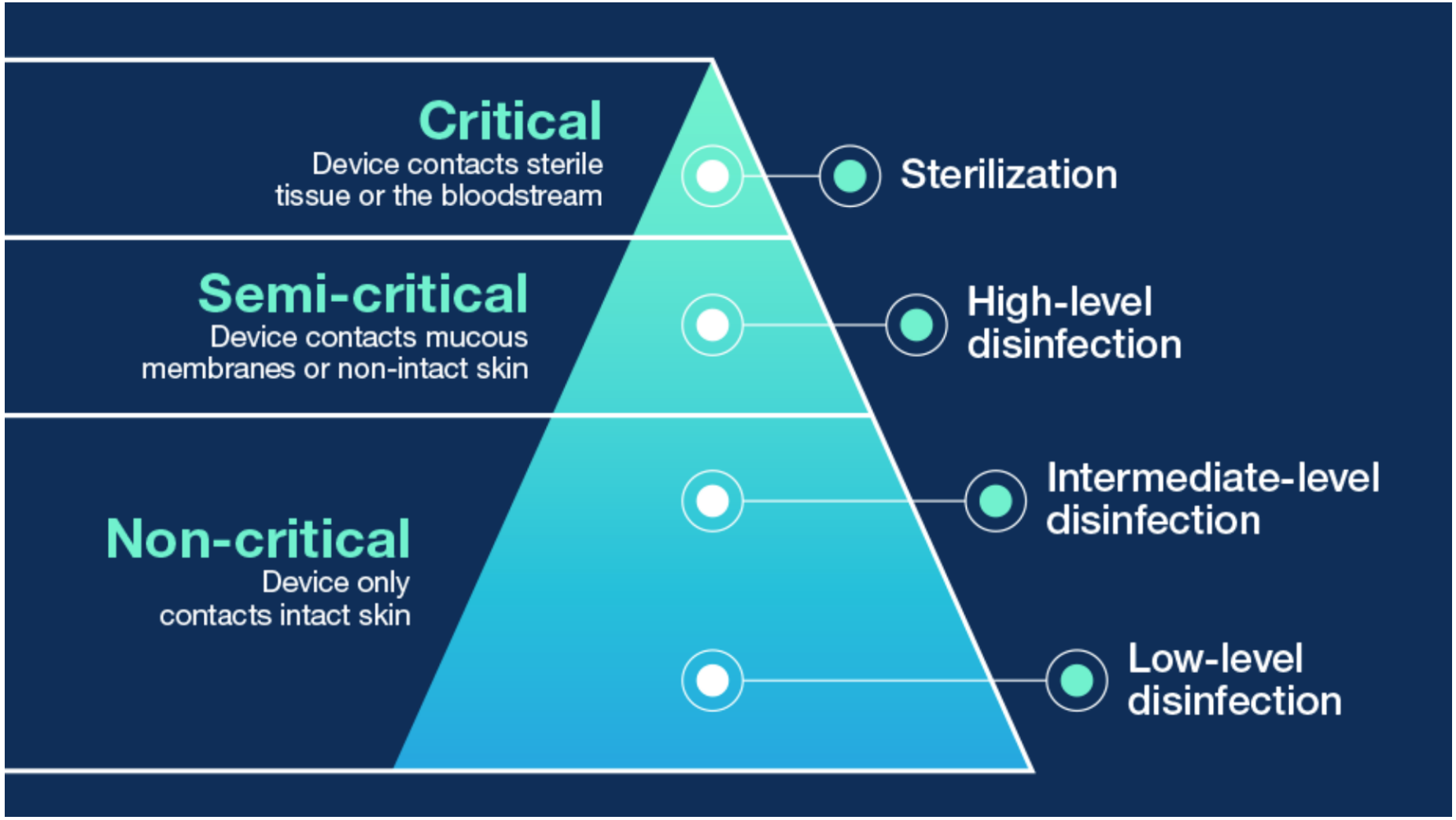
# The Dynamic Ultrasound Landscape

- Proliferation of utilization across many areas and disciplines of medicine
- Wireless ultrasound transducers bring new medical benefits and new challenges
- The breadth of application and innovation is evolving rapidly

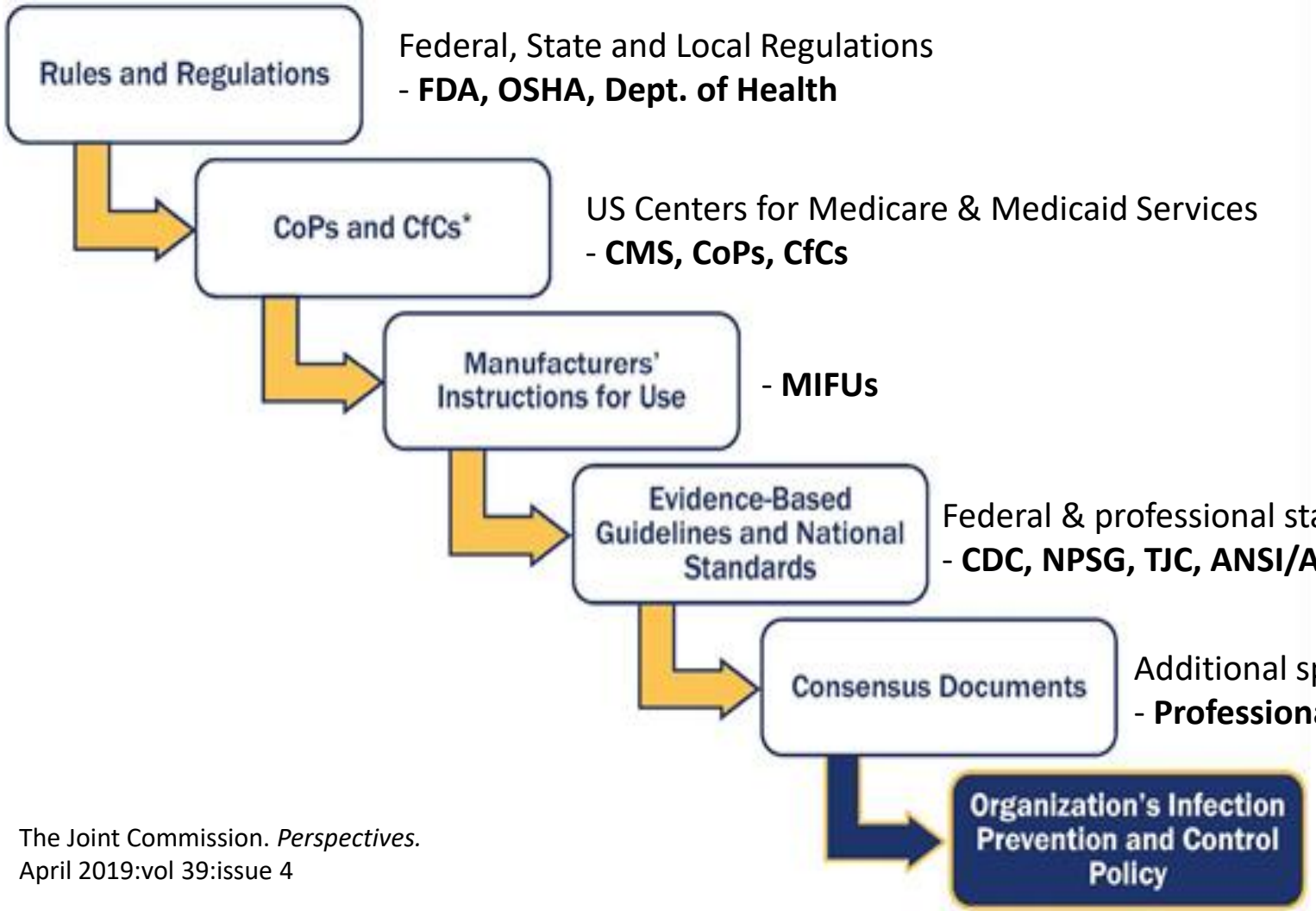
- Some conflicting recommendations across MIFUs, standards, guidelines. How best to resolve?
- How do you properly address infection prevention within the ultrasound environment?
- How do you determine the best methods and practices for your facility?

# The Spaulding Classification System




- The cornerstone of infection prevention
- Foundation of Federal Standards & Guidelines
- Foundation of International Standards & Guidance

# The Joint Commission (TJC)
# The Hierarchal Approach to Standards and Guidelines




Federal, State and Local Regulations
- **FDA, OSHA, Dept. of Health**

US Centers for Medicare & Medicaid Services
- **CMS, CoPs, CfCs**

- **MIFUs**

Federal & professional standard developer stakeholders
- **CDC, NPSG, TJC, ANSI/AAMI, AORN, HSPA (IAHCSMM), WHO**

Additional specific information to reduce patient risk
- **Professional Medical Societies and Organizations**

* Minimum health and safety standards must be met by providers and suppliers participating in Medicare and Medicaid programs

The Joint Commission. *Perspectives.*
April 2019:vol 39:issue 4

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# The Association for the Advancement of Medical Instrumentation (AAMI)

## *American National Standards and Patient Safety*

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# About AAMI's Standards Program

Scope includes a range of issues within health technology

National and international standards development activities

~230 technical bodies and thousands of volunteers

Three types of national documents

- American National Standards
- AAMI Technical Information Reports (TIRs)
- Consensus Reports (CRs)

"User" documents and industry documents

All developed through a consensus process!

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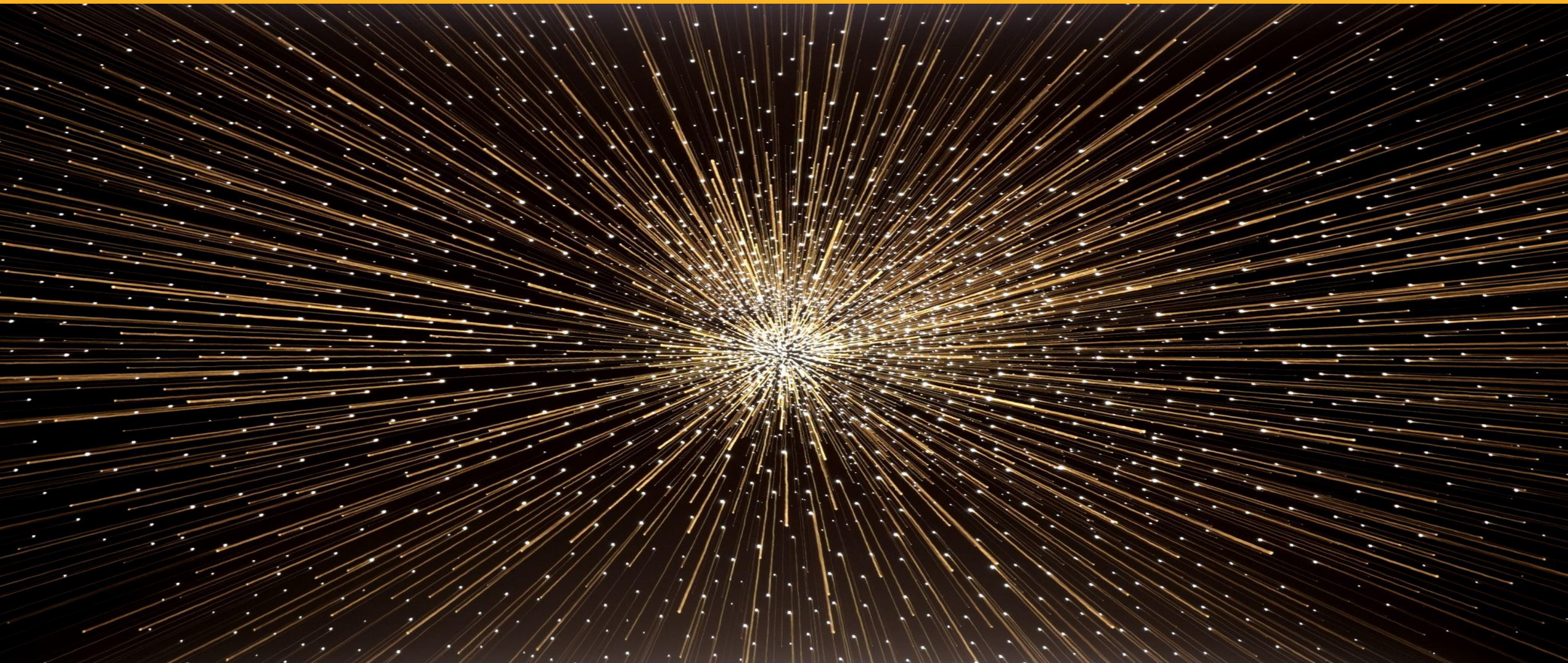
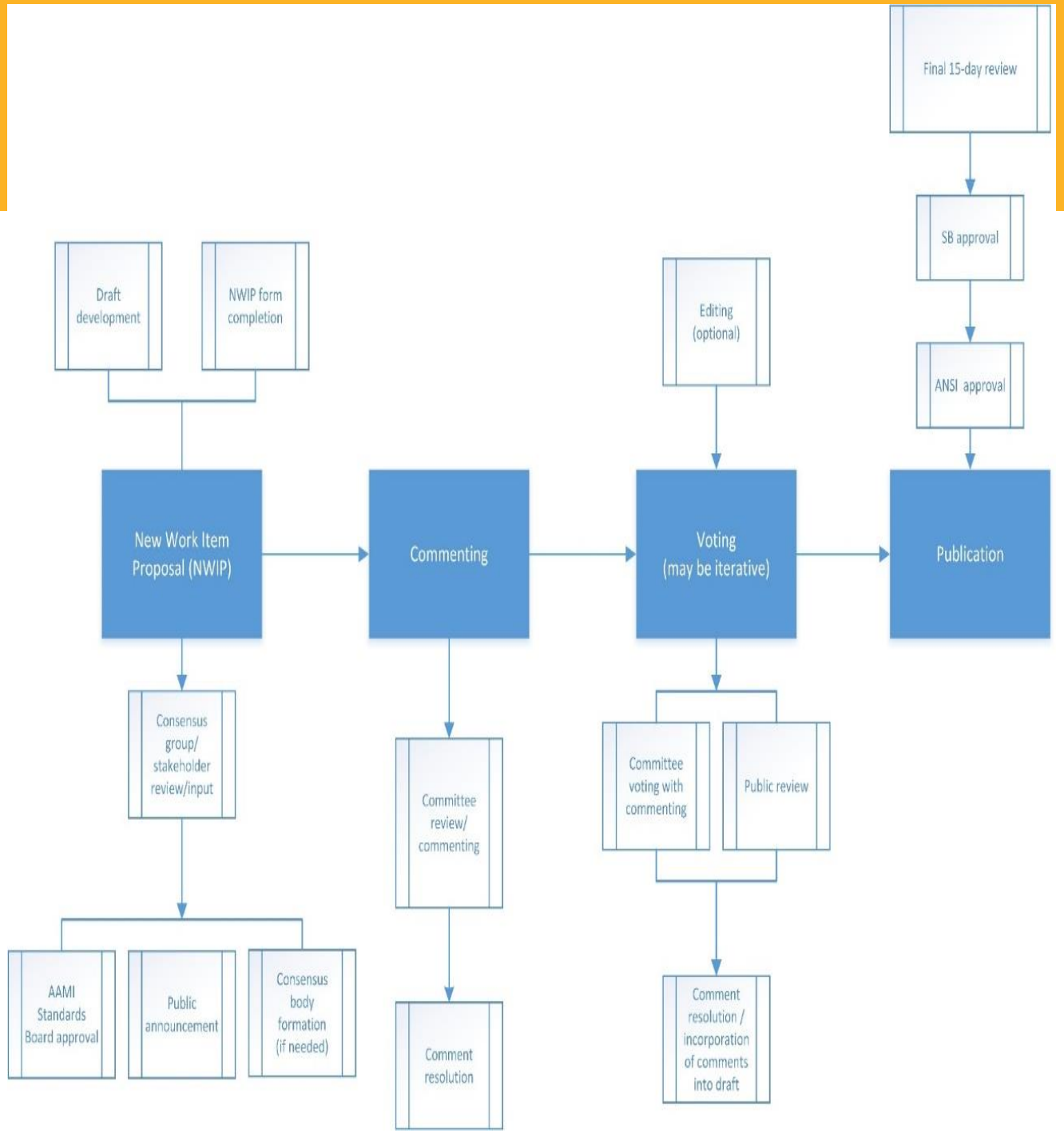
# How are AAMI Standards and Technical Information Reports (TIR) Created?



# It all starts with an idea….

- New work item proposal
- Working draft development
  - Drafting
  - Commenting
  - Comment resolution
  - Iterative drafts
- Committee draft for vote
  - Public review for standards
  - Balloting
  - Commenting
  - Comment resolution
  - Multiple ballots/public reviews?
- Recirculation
- Approval and publication

(NOTE: Consensus reports follow a different process)



# But what about changes and revisions?

- Period review/reaffirmation
  - Every five years for standards
  - Every three years for TIRs
- Revisions can be initiated at any time
- Amendments for small changes to a standard
- Consensus reports can be progressed to a standard or TIR

# But what about changes and revisions?

## Opportunities to add your voice to standards

- Join a committee or working group
- Attend a standards group meeting
- Submit comments during public review
- Propose an idea for a new standard, TIR or consensus report

# NEW - AAMI TIR99: *Dilators, transesophageal and ultrasound probes in health care facilities*

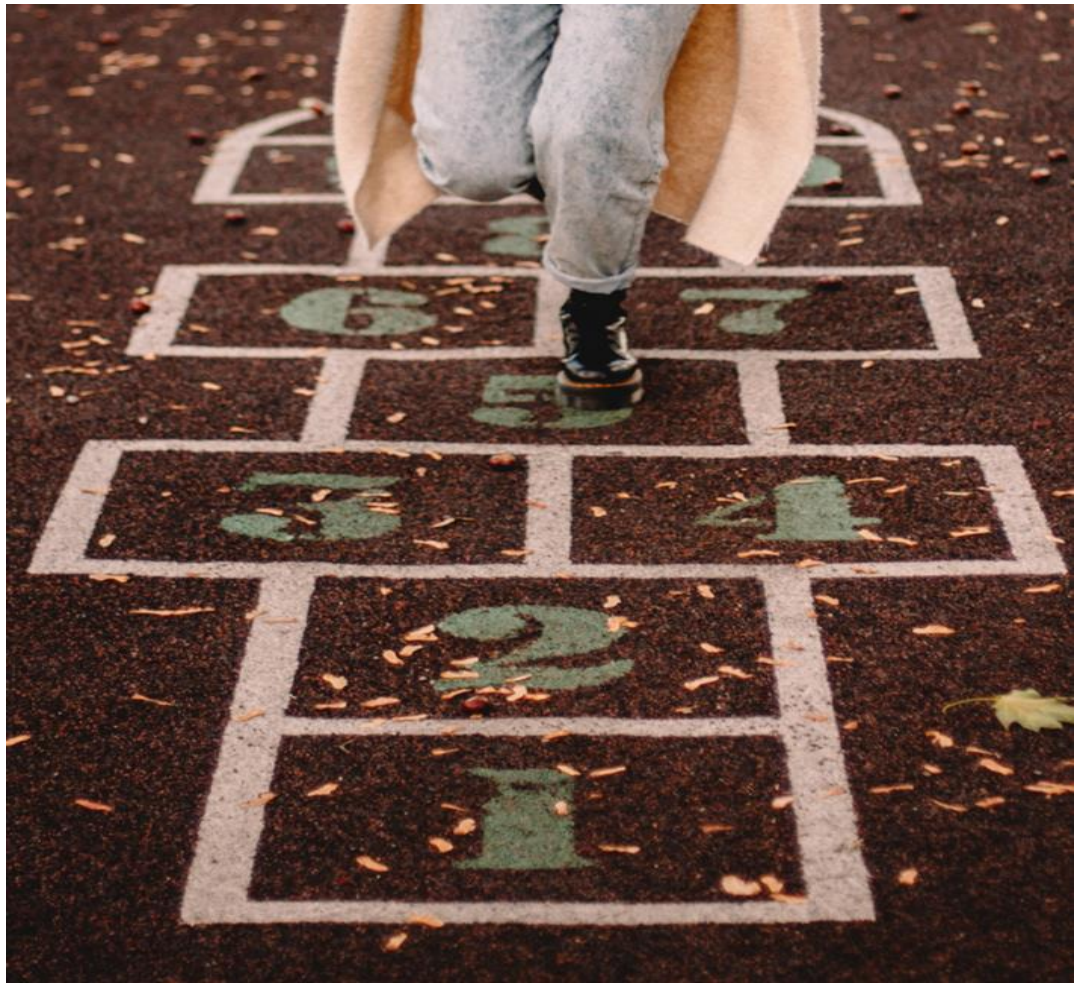
- Guidance for the appropriate processing of dilators and ultrasound probes in health care facilities making them safe for patient care.

- Intended to provide clear and comprehensive information and direction for health care personnel in the processing of these devices and accessories.

# TIR-99: Dilator and Ultrasound Probes Processing in Health Care Facilities – Continued

TIR-99: Dilator and Ultrasound Probes Processing in Health Care Facilities

- Individual steps of precleaning
- Transport both pre and post processing
- Electrical leak testing (if necessary)
- Manual cleaning
- High-level disinfection (both manual and automated)
- Sterilization
- Documentation
- Storage



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# Regulations, Standards and Guidelines in the Development of Policy




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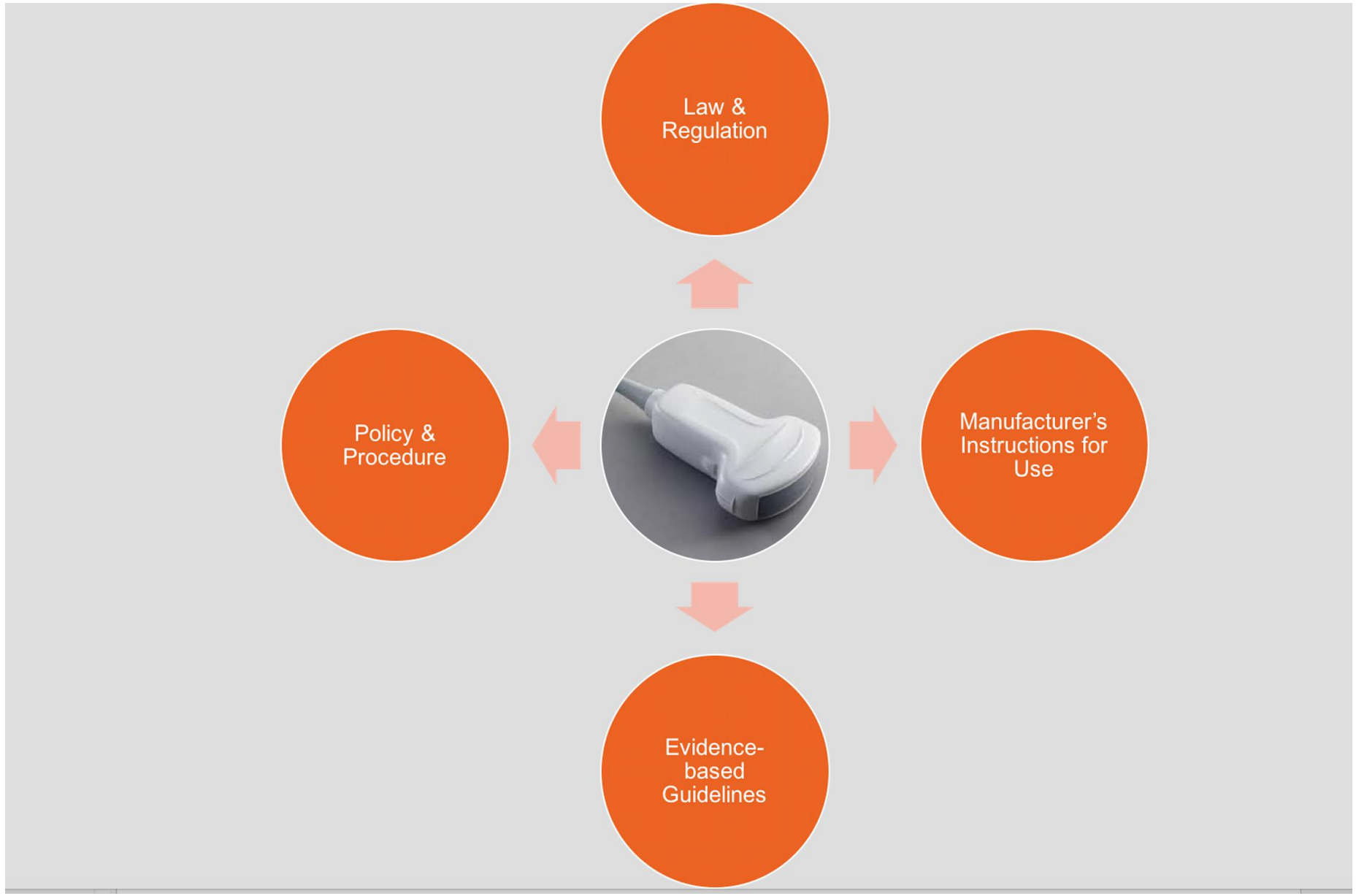
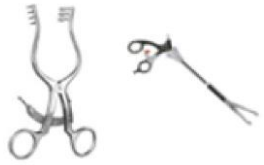
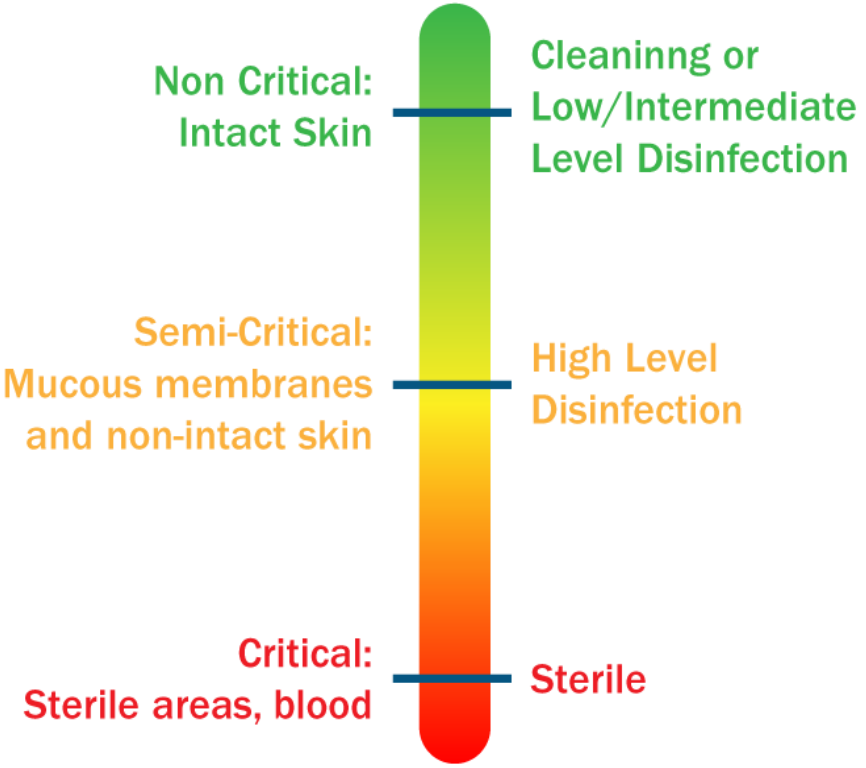

Law & Regulation
Policy & Procedure
Manufacturer's Instructions for Use
Evidence-based Guidelines

# Spaulding Classification

| *Patient Contact* | *Examples* | *Device Classification* | *Minimum Inactivation Level* |
|---|---|---|---|
| Intact Skin |  | Non-Critical | Cleaning and/or Low/Interrmediate Level Disinfection |
| Mucous membranes or non-intact skin |  | Semi-Critical | High Level Disinfection |
| Sterile areas of the body, including blood contact |  | Critical | Sterilization |




Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

# Law & Regulation
## FDA

- Document: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. Guidance for Industry and Food and Drug Administration Staff. Document issued on: June 27, 2019.

- Excerpt from Appendix E: Cleaning, Disinfection and Sterilization

> *The probe used in a **semi-critical application** should be **cleaned and undergo sterilization or at least receive high level disinfection after use even if a sheath was used**. Sheaths can fail during use and the level of resulting contamination may not be easily visible.*

# CMS & The Joint Commission

- **§482.51** Surgical Services.
- **§482.42** Infection Prevention and Control and Antibiotic Stewardship Programs.
- **IC.02.02.01** The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.

  **EP2** Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

# Manufacturer's Instructions for Use (IFUs)

Excerpt from: Philips Care and Cleaning of Ultrasound Systems and Transducers

- *To choose an appropriate care method for your transducer, you first must determine the classification of the transducer, based on its use. The care method for your transducer determines the appropriate disinfectant for your transducer.*

Retrieved from: https://www.philips.co.uk/healthcare/resources/feature-detail/ultrasound-care-and-cleaning#:~:text=Philips%20Ultrasound%20systems%20and%20transducers%20require%20proper%20care%2C,and%20sterilise%20your%20Philips%20Ultrasound%20system%20and%20transducers.

# Manufacturer's Instructions for Use (IFUs)

Excerpt from: GE Transducer Cleaning and Disinfection Guidelines

- *When choosing a disinfectant, determine the required level of disinfection based on device classification. If the possibility of cross-contamination or exposure to unhealthy or non-intact skin exists, then high-level disinfection should be performed.*

Retrieved from: http://www3.gehealthcare.com/static/ge-transducers/GEHC-Guidelines-Transducer_Cleaning_Disinfection_Guidelines.pdf

# Evidence-based Guidelines

ANSI/AAMI ST58:2013 (R2018): Chemical sterilization and high-level disinfection in health care facilities

## 6.6.1 General considerations

- The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents.
- The type of cleaning and/or microbicidal process appropriate for a particular device depends on the manufacturer’s instructions for use.

# Policies & Procedures
## Ultrasound Probe Reprocessing

- Organization-wide
- Reprocessing Steps
  - Point-of-use to storage
- Manual and automated HLD processes
- Documentation
  - Traceability (linking the probe to the patient)
- Competency, training, education
  - Initial and on-going
- Supplies (gel, sheaths)
- References

# Recommendations

- ✓Follow manufacturer’s IFUs.
- ✓Standardize products, supplies, and processes (to include documentation).
- ✓Be knowledgeable of oversight, audits, and validation.
- ✓Standardize selected evidence-based guidelines and P&Ps.

# Why Assure Compliance?

Patient Safety

Risk Management

Accreditation/Survey Readiness

# In Summary

**Law and Regulation**

**Manufacturer Instructions for Use**

**Evidence-based Guidelines**

**P&Ps**

# References


- ANSI/AAMI ST58:2013 (R2018). Chemical Sterilization and High-Level Disinfection In Health Care Facilities
- Rutala W.A., Weber J.A. CDC; Atlanta (GA): 2008. The Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for disinfection and sterilization in health care facilities
- Ultrasound Infection Prevention Toolkit US

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# Q & A

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