International Standard in Sterilization of Surgical Instruments

STERILIZATION OF SURGICAL INSTRUMENTS: FROM BASIC TO ADVANCEMENT

CO ORGANIZED BY INFECTIOUS DISEASE CONTROL TRAINING CENTRE, HOSPITAL AUTHORITY/
INFECTION CONTROL BRANCH, CENTRE FOR HEALTH PROTECTION AND
CHIEF INFECTION CONTROL OFFICER'S OFFICE, HOSPITAL AUTHORITY

SEPTEMBER 30TH, 2021

“There is no shortage of remarkable ideas, what’s missing is the will to execute them.” - Seth Godin

“There is no shortage a standards and guidelines for CSSD / TSSU. What is often in short supply is the time and focus to identify the recommendations or requirements that apply to your practices and the resources to make them stick.” - Janet Prust

Learning objectives

1. Understand the basis and hierarchy between Standards and Guidelines for instrument processing

2. Review QMS and Risk Management approach for instrument processing

3. Highlight key current practice points as described by current Standards and Guidelines

Janet Prust - Disclosure

Employee of 3M Health Care -

Medical Solutions Division

- US delegation leader for ISO TC 198 – Sterilization of medical product
- AAMI Chair-elect for Board of Directors; AAMI Foundation Board Chair
- Global Standards Director for 3M Medical Solutions Division.
- Over thirty years of health care and industrial sterilization industry experience with clinical practice experience prior to joining 3M
- Clinical Science degree from the University of Minnesota with several healthcare related certifications including CRCST.
- Associate or industry member of IAHCSMM, ASTM, APIC, EOSA, SGNA, AORN, AHRMM and other several other professional organizations.

International Standard for Sterilization of Surgical Instruments – Does it exist?

Is it a Standard or Guideline?

STANDARD	PRACTICE GUIDELINE	GOVERNMENTAL
Consensus Standard Setting Organization	Professional/Medical Society or Organization	Regulations
Stakeholder committee participation	Single Specialty Area **Some multi-society*	Specifications (MOH tenders)
Define **requirements** for performance for device or system	**Recommendations**	Recommendations
Regulatory recognition/impact	Specialty Committee or Society Staff	National or Area
National, Area, or Global	National	Compliance Mandate
Data, expert consensus, other standards based	Graded evidence, other guidelines, experience based	

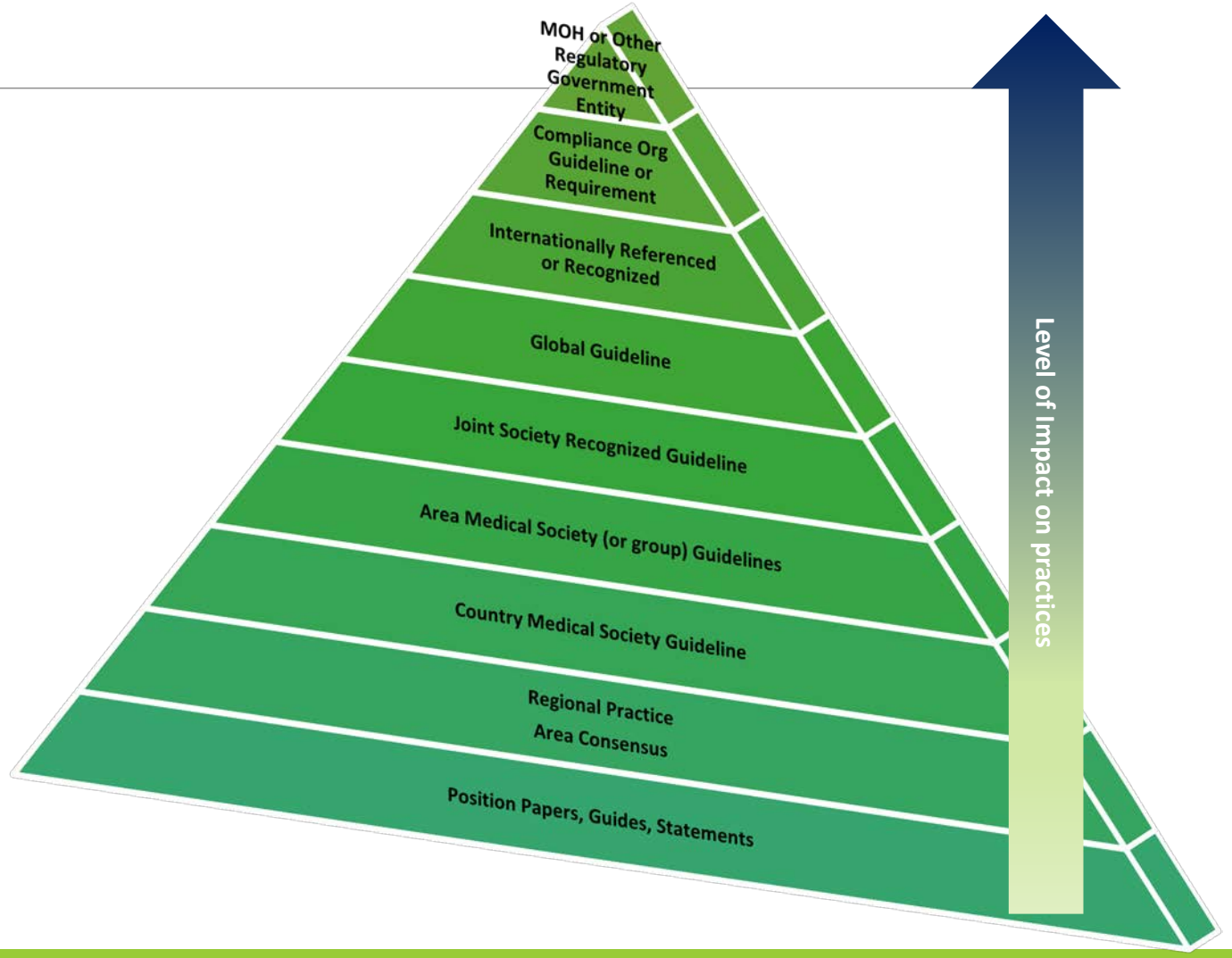
Global Clinical Practice Guidelines

Clinical Practice Guidelines take many forms:

- **Guideline**
- **[Position] Statement/ Guide**
- **Consensus Document**
- **Textbook**
- **Tool Sets**
- **Algorithm**

Key Non-Medical Society Guideline Authoring Entities

Entity	Influence
WHO	Global
US CDC	Global
JCI	Developing
NICE (National Institute of Health)	UK NHS



Guidelines are offered in many different means with varying levels of adherence and impact on practices.

Standards Development Organizations (SDO)

SSOs differ from Professional Medical Society/Organizations as *their primary activity is to establish standards*. The SDO committees are volunteer or member consensus groups representing of a variety of relevant stakeholders that establish standards.

The standards produced by SSOs typically fit into three categories important to the medical industry:

Practice = Recommended healthcare practices for patient or environment of care

- **Examples:**
  ANSI/AAMI ST79**:** Steam sterilization and sterility assurance in healthcare facilities. 2017.
- AS/NZS 4187: 2014 Reprocessing of reusable medical devices in health service organizations + Amendment 2 (2019).
- CSA/Z314-18: Canadian medical device reprocessing

Performance = Validation and testing requirements, characteristics and performance of materials, products, systems and services

- **Examples**:
- ISO 11138: Sterilization of medical devices – Biological indicators – General requirements
- IEC 61010 Series: Safety requirements for electrical equipment for measurement and control and laboratory -
- ASTM F1980-16: Standard guide for accelerated aging of sterile barrier system for medical devices

Quality Systems = Guidance or regulations for quality management requirements for Medical Device Manufacturers and Increasing application in healthcare

- **Examples**:
- ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
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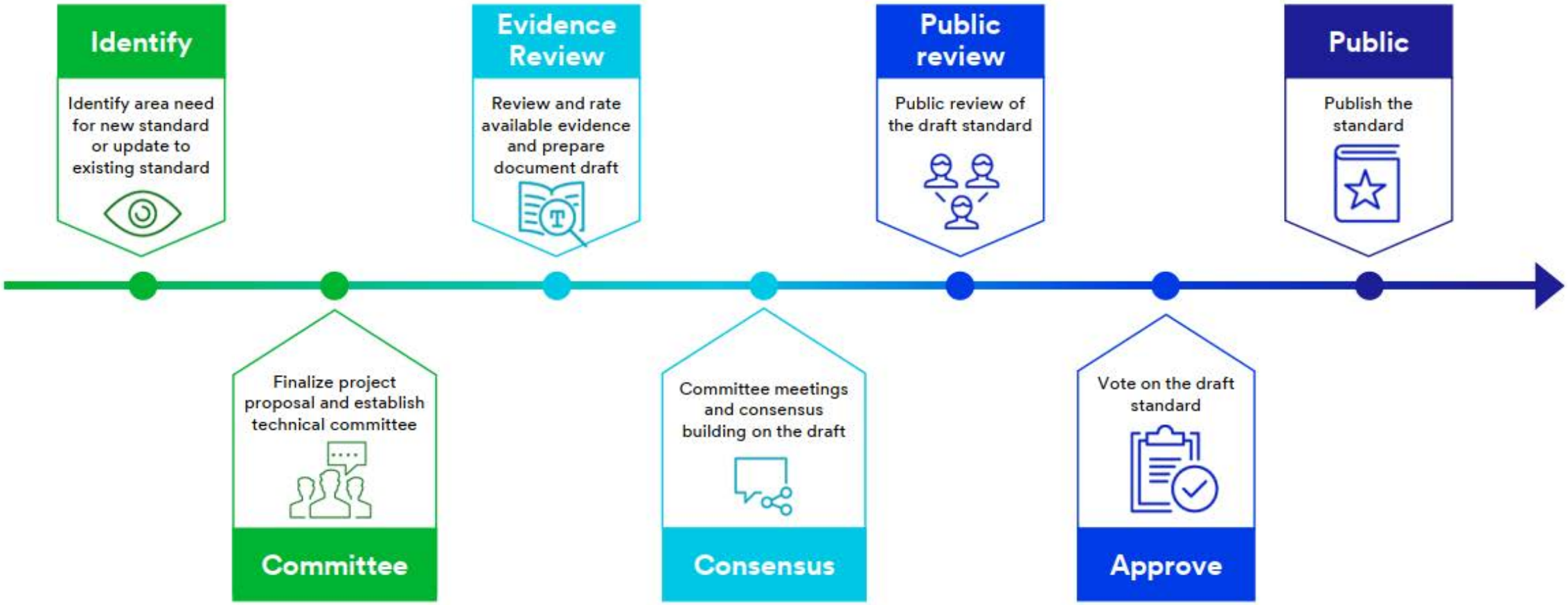
- AAMI ST 91: Processing of health care products – Quality management systems for reprocessing in healthcare facilities

Practice Standards are similar in scope to Practice Guidelines but authored by SDO – not a Prof Medical Society.
CSSD is one of the few practice areas have SDO Standards in addition to Prof. Medical Society author Guidelines.

Standards and Guideline Development & Review Process



Distinct Processes With the Same Goal

Activity	Consensus Standard	Clinical Practice Guideline
Full Stakeholder participation	Yes	No Other stakeholders provide input during public review
Developed and published by Standards Development Organization (SDO)	Yes	No. Developed by professional/medical society or joint societies Published by society or specialty journal.
Guidance for CSSD practices	Yes – US AAMI standards, CSA standards, US Equipment Service Standards for Health care	Yes
Guidance for product or process performance requirements	Yes	No Strong reference to product manufactures Instructions for Use
Covered by Vienna Agreement and Global harmonization strategies	Many	No
Basis for content	Expert consensus opinion + data+ regulatory guidance + evidence where available	Published evidence with expert opinion where evidence is lacking. Strength of recommendation often graded.
Key Organizations	ISO, IEC, AAMI, ASTM, CEN, SA and other National Standards bodies/NSBs, etc.	APSIC, JSMI, other CSSD or IP member Societies
Example of documents	ISO/CEN/AAMI/ANSI 11135 – Sterilization of health care products — Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices ISO/CEN/AAMI/ANSI: 13485 – Medical Devices – quality management systems – requirements for regulatory purposes	**APSIC** - The APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities. 2017. :

What is Consensus and Who are the Stakeholders????

Substantial agreement between individual [committee members] and organizations having a direct and tangible concern with the standard or document = stakeholder *

From ISO: A document, established by **consensus** and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, ***aimed at the achievement of the optimum degree of order in a given context.***

Establishing consensus entails:

A. Substantial agreement, by written ballot, among committee members (aligned *with ISO/IEC requirements).*
   - Approval by at least a majority (2/3 or those voting) excluding abstentions
   - Ballots returned by 2/3 or all voting committee members to achieve a successful ballot
   - Desired to be representative of the interest category composition of the committee

B. Public review

C. Resolution of comments

D. Consensus requires all views and objections be considered and responded to and a concerted and documented effort was made toward comment resolution.

E. Consensus DOES NOT require that all objections are withdrawn and/or all votes are affirmative

Stakeholder: Individual, or group of individuals, with interests that may affect, or be affected by, an organization (from ISO 26000: 2010, definition 2.20).

Defined by Standards Development Organizations (ISO, AAMI Standards Board, AAMI Board of Directors, ANSI Board of Standards

Global / International Standards and Guidelines

Global Guidelines

World Health Organization + Pan-American Health Organization

Global representation of
Medical professionals + WHO staff

Addresses entire process
Evidence based
Focus on requirements for economically challenged areas

Updated as needed

International

ISO/ IEC

Consensus Process of Stakeholder groups of member country participants;

Industry 60+%, Health Care User ~20%, Regulators <5%, Other experts ~ 5%

5- year cycle – reaffirm/ update or obsolete.

Some standards 'recognized' by regulatory authorities; Notified bodies inspect to certify or 'attest' to compliance for industry; CEN adoption enforced by local health authorities in EU countries

Globally Recognized

US CDC

Primary author (s) designated subject matter expert
Reviewed by CDC HICPAC Committee

Comprehensive Process and Evidence Review

Updated as needed

Key CSSD Standards and Guidelines

Key APAC Guidelines

- **APSIC** The APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities. 2017.
- **JSMI** Guideline for Sterility Assurance in Healthcare Setting. 2021.
- **Korea** KACSDN CSSD Clinical Practice Standard Guideline Ⅲ. 2018
- **Standards Australia AS/NZS 4187**: 2014 Reprocessing of reusable medical devices in health service organizations + Amendment 2 (2019).

Global Guidelines

WHO + PAHO Decontamination and Reprocessing of Medical Devices for Health care Facilities. 2016.

US CDC Guideline for Disinfection and Sterilization in HC facilities, 2008. Update May 2019.

US ANSI/AAMI and Canada

ANSI/AAMI ST 79: Steam sterilization and sterility assurance in health care settings. 2017 & 2020, A1, A2, A3, A4.

ST 58 Chemical sterilization and high level disinfection in healthcare facilities. 2013.

ST 91: Flexible and semi rigid endoscope processing in health care setting. 2016.

ST 90 ANSI/AAMI ST90: Processing of health care products Quality management systems for processing in health care facilities. 2017.

CSA/Z314 18: Canadian medical device reprocessing. 2018.

New in development:

New ST 98 Water Quality

ST xx Steam sterilization for dental facilities (draft title)

ISO Standards TC 198 Sterilization of Medical Devices:

- 17665 Moist Heat Requirements for the development, validation and routine control of a sterilization process for medical devices series. 2006.
- 15883 Washer disinfector/ (includes Endo reprocessor) series
- 13485 Medical Devices Quality Management Systems Requirements for regulatory purposes. 2016.
- 11607 - Packaging for terminally sterilized medical devices series
- 11138 Biological indicators series
- 11140 Chemical indicators series
- New in development at ISO:
  - TS 5111 Water Quality TS 5111
  - 22441 VHP processes
  - 11138 Part 8 VHP BI
  - 11140 Part 6 Type 2 indicators and PCD for use in performance testing of small steam sterilizers

Update in process.

European Standards

UK Health Technical Memorandum
CFPP 01 01 Series Decontamination
CFPP 01 06 Series Endoscope processing

EN documents are requirements for EU countries only to meet EU Medical Device Regulation. Does not apply to HK or other countries.

ISO TC 198 Sterilization of Medical Devices - Working Groups

Committee ID	Committee Name	Key Standards; in process
ISO/ TC 98 WG 1	Industrial ethylene oxide sterilization	ISO 11135 – update in process
ISO/ TC 98 WG 2	Radiation sterilization	ISO 11137 – update in process
ISO/ TC 98 WG 3	Moist heat sterilization	ISO 17665 – update in process
ISO/ TC 98 WG 4	Biological indicators	ISO 11138 – new Part 6 – VHP BI in process
ISO/ TC 98 WG 5	Terminology	ISO 11139 – amendment in process
ISO/ TC 98 WG 6	Chemical indicators	ISO 11140 -
ISO/ TC 98 WG 7	Packaging	ISO 11607
ISO/ TC 98 WG 8	Microbiological methods	ISO 11737
ISO/ TC 98 WG 9	Aseptic processing	ISO 13408
ISO/ TC 98 WG 10	Liquid chemical sterilization	ISO 14160
ISO/ TC 98 WG 11	General criteria for sterilization processes	ISO 14937
ISO/ TC 98 WG 12	Information for reprocessing of medical devices	ISO 17664
ISO/ TC 98 WG 13	Washer-disinfectors	ISO 15883
ISO/ TC 98 WG 15	Assurance of sterility	ISO/TS 19930
ISO/ TC 98 WG 16	Vaporized hydrogen peroxide sterilization	In development
ISO/ TC 98 WG 1	Technical committee – Sterilization of Medical Devices	TS 5111 – Water quality in sterilization of medical devices

ISO Harmonization Philosophy and Gaps for CSSD

One standard for all processes types – no matter WHERE the process is performed or WHAT is processed by WHOM with ANY equipment

	Types of devices	Soil/ bioburden	Packaging	Load	Cycles	Equipment validation and maintenance	Resourcing	Regulated
Healthcare	Wide range of devices, manufacturers, usage	Wide range	Mixed	Wide range	Wide range based on sterilizer and device needs. HC does not develop cycle.	CSSD manager Contracted service providers	Challenged typical of healthcare structures	Limited
Industrial	Single use, only manufacturers line of products; Validation of reusable for IFU	No patient generated soil. Bioburden minimized and controlled.	Homogenous	Single type disposable	Limited. Develops custom cycle for product family.	Sterility assurance engineers and microbiologists	Specialized technical skill sets	Yes

Validation and Verification – What is the difference?

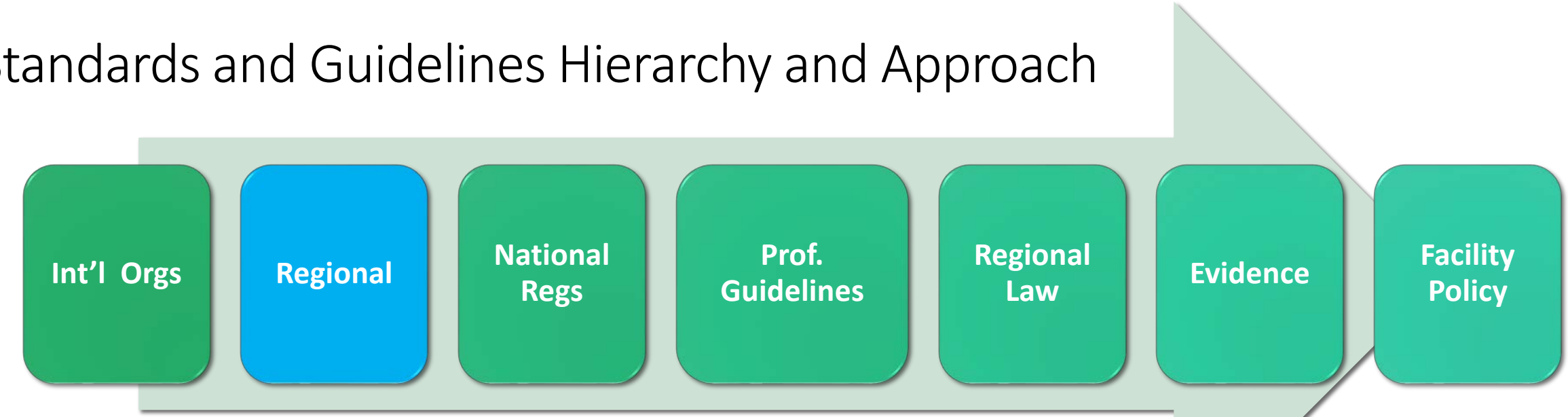
AAMI ST 79: 2.131 Validation: Documented procedure performed by the device manufacturer for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

AAMI ST 2.129 User verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met

ISO 11139: **3.313 Validation**: Confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

ISO 11139: 3.314 **Verification:** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Standards and Guidelines Hierarchy and Approach



What	ISO Medical Device Sterilization Standards	Evidence Based Practices
Processes	Validated with periodic revalidation	Verified and routinely, objectively monitored
Equipment	Qualified, annual calibration and maintained	Qualified and maintained
Personnel	Training	Training and competency assessment
Approach	Consensus applying to both industrial and healthcare setting	Data and outcomes in clinical setting addressing the entire process

Emerging/ hot/ research topics for instrument processing

1. Practices in Dental and Physician clinical based setting
2. Quality management system for CSSD
3. Risk based approach with plan/do/check act or other CQI approach
4. On-going challenges with reprocessing flexible endoscopes and robotic instruments – all types
5. Water quality – cleaning, rinsing, mechanical washers, water for steam purity
   - More recent focus on air quality
6. Staff training and competency assessment
7. Focus on meticulous cleaning – point of use care, cleaning monitoring, flexible endoscopes and complex instruments
8. New technologies – sterilizers, sterilization monitoring, automation, high level disinfection equipment (e.g. drying lumens and flexible endoscopes)
9. Electronic documentations – tracking and traceability
10. Package integrity through repeated handling (current research project through Killmer Innovation)

Quality Management System for CSSD

WHO & PAHO – Define the Essential Elements of QMS

- Procedures and recordkeeping for Decontamination and Sterilization: Sterilizer monitoring with BI and CI controls, sterility release criteria with validated process parameters, device tracking and traceability, storage and transport, preventative maintenance, current policy and procedures based on knowledge of current standards, IP controls, Occupational health and safety policy and procedures, PPE, Education and Training, Risk Management, Auditing

ANSI/AAMI ST 90 – Specific to CSSD setting

ANZ NSQHS Standard 3 – Within infection control requirements

ISO 13485 – Intended for medical device manufacturers

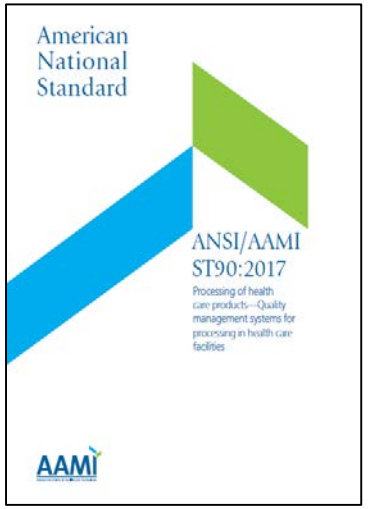
- World Health Organization and Pan American Health Organization: Decontamination and Reprocessing of Medical Devices for Health-care Facilities 2016
- ANSI/AAMI ST 90:2017 Processing of health care products – Quality management systems for processing in health care facilities
- Australian Commission for Safety and Quality in Health Care. NSQHS Standard 3: Preventing and controlling health care associated infections. Safety and Quality Improvement Guide.
- International Standards Organization/ ISO. 13485 – Medical Devices – Quality Management Systems – Requirements for regulatory purposes. 2016.

Key QMS Standards for ICP and CSSD

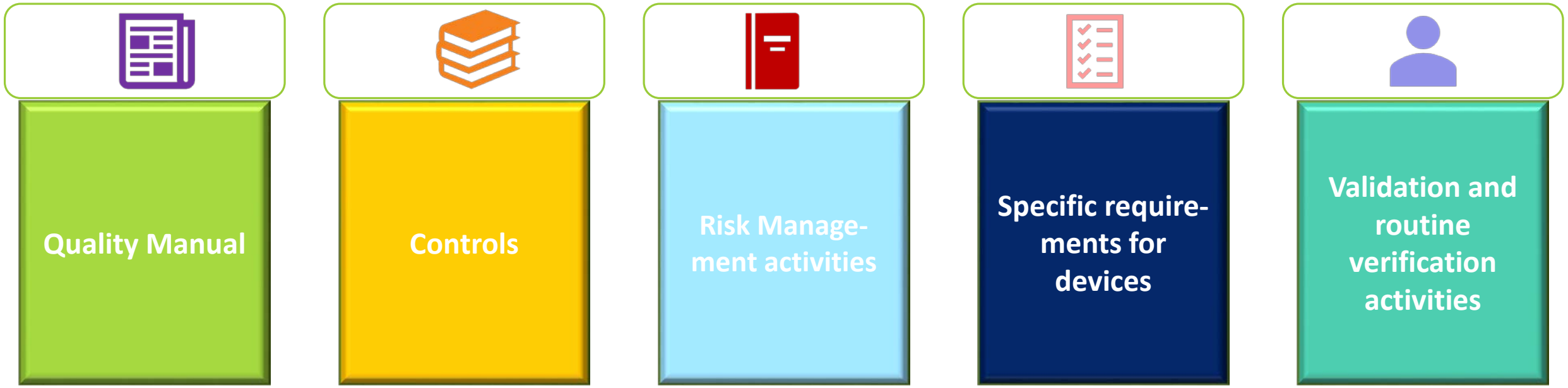
NSQHS Standard 3: Preventing and controlling health care associated infections. Safety and Quality Improvement Guide. 2nd Edition. 2018.

ANSI/AAMI ST 90:2017 Processing of health care products – Quality management systems for processing in health care facilities

- US standard specific to reusable medical device processing.
- Annex B provides comprehensive information for Risk Management

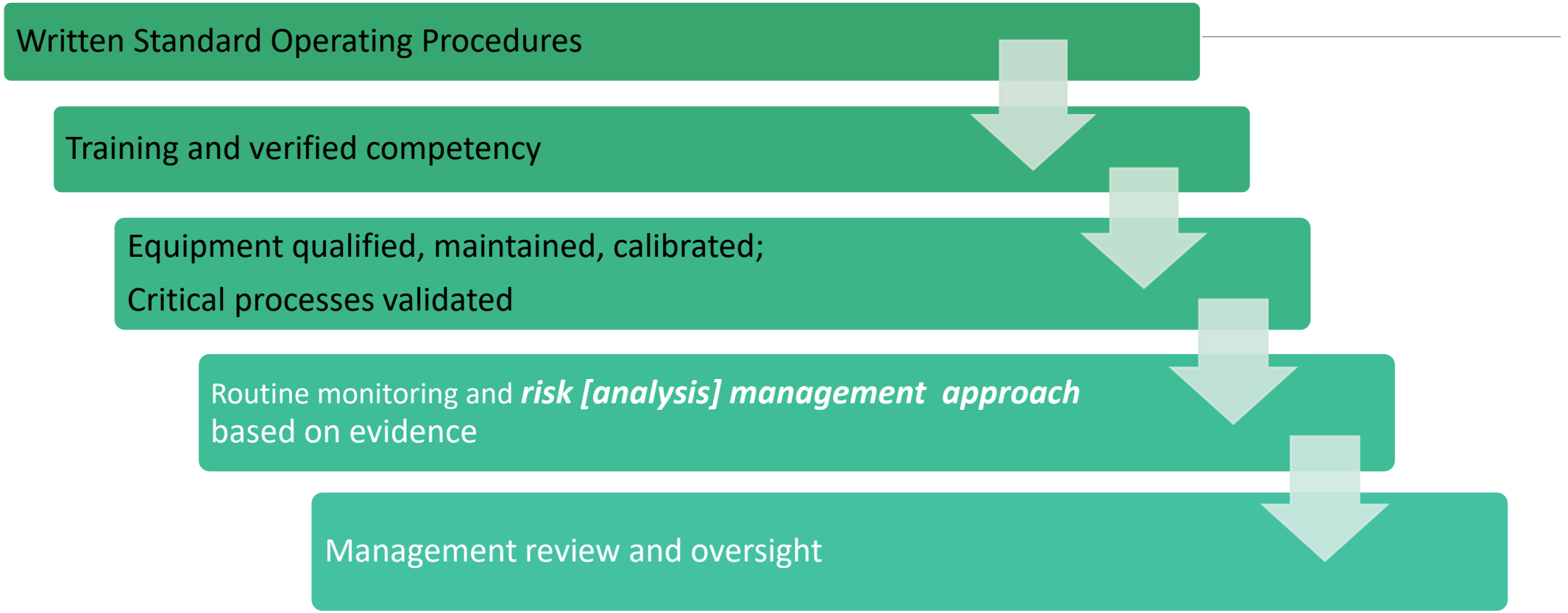


CSSD Quality Management System Pillars



Australian Commission for Safety and Quality in Health Care. NSQHS Standard 3: Preventing and controlling health care associated infections. Safety and Quality Improvement Guide.
ANSI/AAMI ST 90:2017 Processing of health care products – Quality management systems for processing in health care facilities

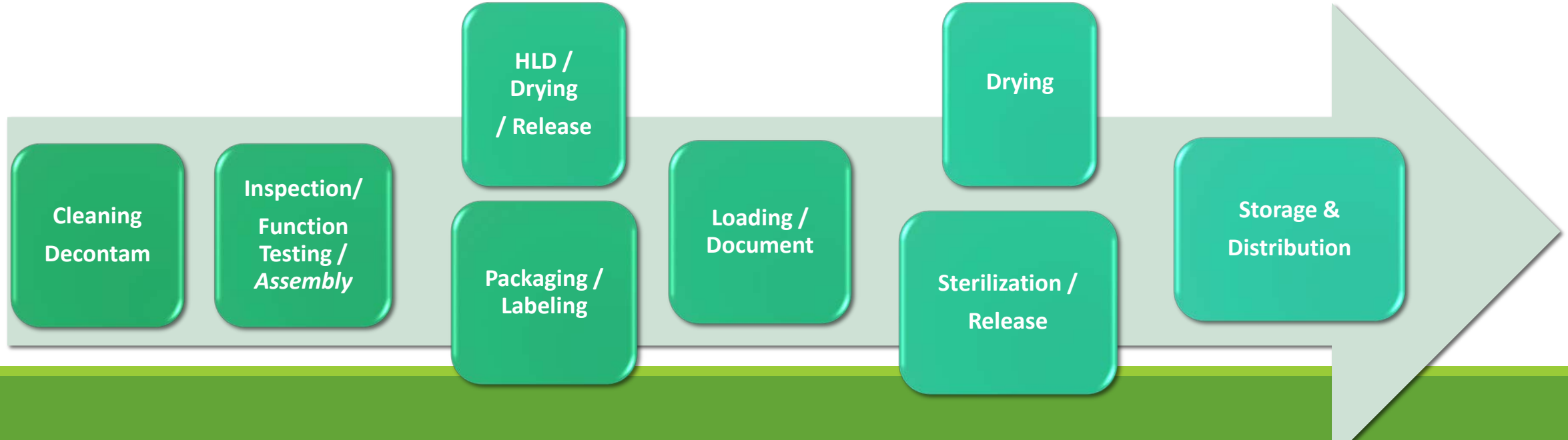
Quality Management System for CSSD Components



AS/NZ 4187:2014. Reprocessing of reusable medical devices in health service organizations
ANSI/AAMI ST 90:2017 Processing of health care products – Quality management systems for processing in health care facilities

Risk Analysis Process for CS

1. Identify all critical risks in process steps
2. Describe what could reasonably go wrong
3. Determine how often it could occur
4. Determine the impact of the problem if it occurs
5. Identify relevant evidence to determine risk and mitigation
6. Implement preventative action (e.g. quality control) to avoid or reduce the risk
7. Develop plan to mitigate the risks of something goes wrong



Known Reprocessing Risks

1. Instruments requiring extended cycles
2. Improper point-of-use care
3. Delayed reprocessing
4. Flexible endoscopes not properly processed for patient use
5. Late arrival of loaner instruments to allow for reprocessing according to IFU and quarantine implants for BI results
6. Practice vs policy & procedures / guidelines / evidence
7. Early release of implants
8. Prion contamination devices
9. Immediate use steam sterilization (IUSS)
10. Robotics – complexity to reprocess
11. Wrong BI process challenge device is run during routine testing
12. Improperly reprocessed eye sets with increased risk for TASS
13. Less than daily verification of mechanical cleaning equipment
14. Manufacturer's IFU for cleaning not followed

Young, Martha Top 10 Risk in Sterile Processing. AAMI Horizons Spring 2012

Risk Assessment of the Sterilization Process

Sample Risk Findings

1. Undetected debris in lumens
2. Delay in processing flexible endoscopes
3. Sets sent to SPD/CSSD with dried-on debris
4. **Early release of implants**
5. Receiving loaners, the day of surgery
6. Not enough eye sets for the day's surgery
7. Instrument sets over 10 kilo (7 EU)
8. IFUs not always available

Newer/ Key Focus in Guideline Recommendations - Transport and Cleaning

- Validation of equipment and processes
- Ensure point-of-use treatment
- Pay attention to water quality
- Monitor processes – mechanical and manual
- Secure, clean transport
- Electronic documentation and traceability
- Utilize mechanical cleaning as much as possible
- Follow instrument manufacturers IFU for cleaning instructions – process, detergents, type, etc.

High Level Disinfection / Endoscope Reprocessing – Focus in newer Guidelines

- Point of use care (‘pre-cleaning)is critical
- Lighted, magnification for visual inspection for damage and debris
- Cleaning verification for high risk endoscopes
- Monitor HLD processes – automated and manual
- Electronic documentation and traceability; load documentation
- Follow instrument manufacturers IFU for process compatibility
- Ensure thoroughly dry PRIOR to storage
- Define facility hang-time policy

Inspection and Packaging – Newer/key Focus in Guidelines

Validation of equipment

Lighted magnification to detect residual soil or damage

Compatible packaging for sterilizer process type

Electronic documentation and traceability and packing instructions; package labeling

Follow instrument manufacturers IFU for packaging and accessory compatibility

Steam Sterilization - Newer/key Focus in Guidelines

- Validation of steam sterilizers – IQ, OQ, PQ, Requalification
- Routine verification with equipment, pack and process Monitoring
- Ensure cool and dry
- Monitor processes
- Electronic documentation and traceability; load documentation
- Follow instrument manufacturers IFU for process and cycle compatibility

Low temp sterilization - Focus in Guidelines

Validation of low temperature sterilizers – IQ, OQ, PQ, Requalification	Routine verification with equipment, pack and process monitoring	Ensure compatibility to cycle and packaging, accessories
Ensure proper loading	Electronic documentation and traceability; load documentation	Follow instrument manufacturers IFU for process and cycle compatibility

Load Release Options:
Routine Monitoring or Parametric Release or Both?

Both approaches require:

- A Quality System consisting of policies & procedures for reprocessing of medical items with provisions for appropriate documentation
- A sterility release mechanism based on physical parameter (temp and pressure) results and evidence or reprocessing per specifications

Parametric release also requires:

- Rigorous and thorough validation of the entire process (including re-validation)
- Strict adherence to the validated process and rigorous calibration and maintenance of equipment
- Preferred option in industrial sterilization settings

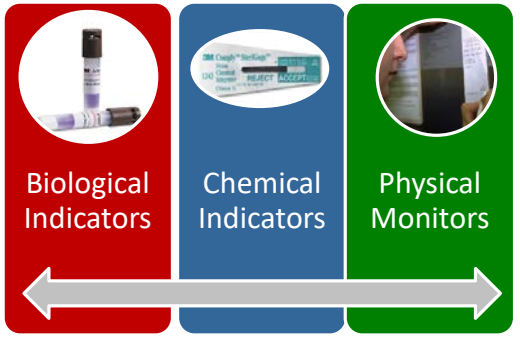
Routine monitoring also requires:

- Rigorous use of physical parameter, chemical (equipment and pack, and biological indicators in process challenge device
- Preferred option throughout much of the world to address the known variability in devices, loads, cycles, equipment, resources and competency

Routine Monitoring

Sterilized load release is based on:

- Integration all monitoring control results



- Verification of appropriate reprocessing procedures and documentation per the requirements of the Quality System

Quality Control Monitors – What can they detect?

Monitor	Failed cycle result	Detects	Cause indicated	Action to take
Mechanical/ Physical	Inadequate temp, time or pressure Cycle error code	Cycle conditions were not met	Equipment malfunction	Shut down sterilizer, hold load Re-run with test load Contact Service maintenance
Exposure Control – External chemical indicator	Indicator tape does not turn dark	Item was not exposed or inadequately exposed	Equipment malfunction Improper loading Improper cycle selection	Rerun package Begin investigation
Pack Control – Internal pack chemical indicator	Fails to reach end point color or provides a 'reject' result	Critical parameter not met in package	Inadequate cycle parameters – equipment malfunction	Quarantine package Check other packages in same load/ rerun Begin investigation
Load Control – Biological Indicator in test pack PCD in load	Positive result	Cycle was not lethal	Poor steam quality or purity Equipment malfunction Improper loading Improper cycle selection	Quarantine load/ recall Begin failure investigation
Load Control – Chemical indicator in test pack PCD in load	Fails to reach end point color or provides a 'reject' result	Critical parameter not met in test pack		Quarantine load/ recall Begin failure investigation
Equipment Control – Bowie-Dick type test	Fails to achieve uniform color change	Inadequate air removal or steam penetration	Equipment malfunction	Shut down sterilizer, hold load Re-run with test load Contact Service maintenance

Quality Control monitoring provides more information regarding the cycle, assurance of sterility and procedures where followed than reliance on validation only with physical monitoring.

Ensure your organization is working collaboratively at defining and implementing current recommendation for instrument processing.

When everyone rows together you can improve practices for the patient.

Thank you for your time and attention!

Reference Citations for Guidelines and Standards

1. Asia Pacific Society for Infection Control. The APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities. 2017.
2. KACSDN CSSD Clinical Practice Standard Guideline Ⅲ. 2018
3. Standards Australia. S/NZS 4187: 2014 Reprocessing of reusable medical devices in health service organizations + Amendment 2 (2019).
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15. International Standards Organization/ ISO. 11138 series. Sterilization of Medical Devices - Biological indicators. Publication dates vary by part.
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