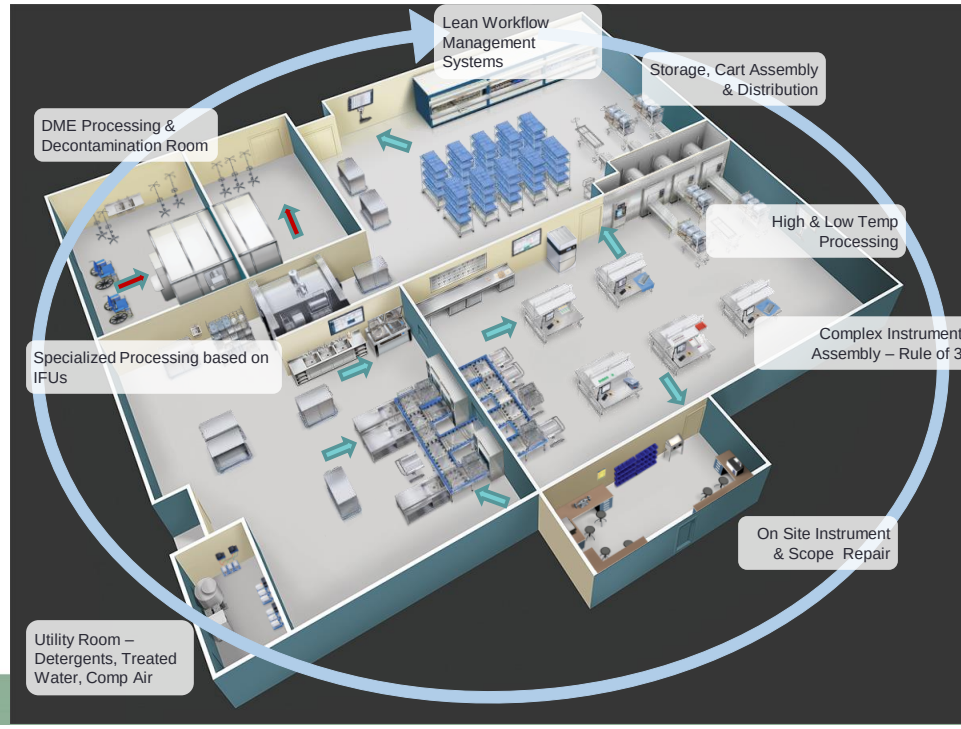
QUALITY MANAGEMENT SYSTEMS IN THE SPD

Why You Need It and How to Get There

Lena Cordie, Qualitas Professional Services, LLC.
Richard Schule, STERIS Corporation

Learning Objectives

- **Understand concept** of quality management systems (QMS):
  - What are they
  - Why are they important for sterile processing
  - What are the benefits of implementing a QMS
  - How can a QMS be implemented in SPD
- **Learn strategies** for shifting to a quality approach for sterile processing and how to manage that change in your SPD
- **Gain awareness** of the new ANSI/AAMI ST90 as an important resource to operationalize QMS in the SPD



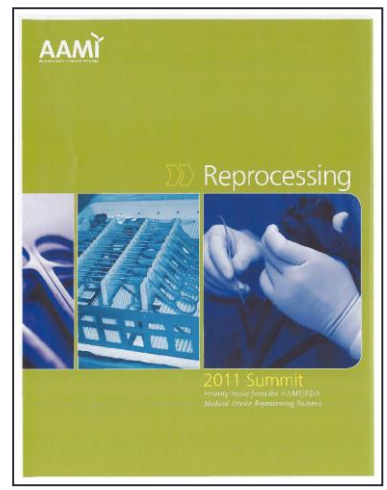
How Well Does Your Department Support Patient Safety?

The Story Behind ST90:
From Concept to Draft to Standard

The Spotlight on Reprocessing

"No one group can do this alone, and the answer is not as simple as "more standards" or more "regulations."

Mary Logan
AAMI President
2011 Summit Publication

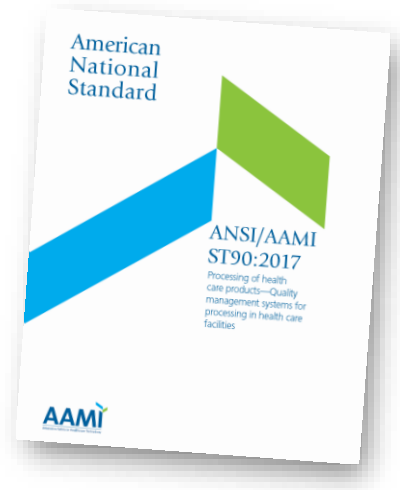


AAMI/ST/WG86:
Quality systems for device reprocessing

- ✓**Support** quality management systems for reprocessing of reusable medical devices in hospitals and other health care facilities
- ✓**Promote** quality processes and methods
- ✓**Assist** health care personnel in the proper application of a QMS
- ✓**Achieve** acceptable reproducible events

ANSI/AAMI ST90

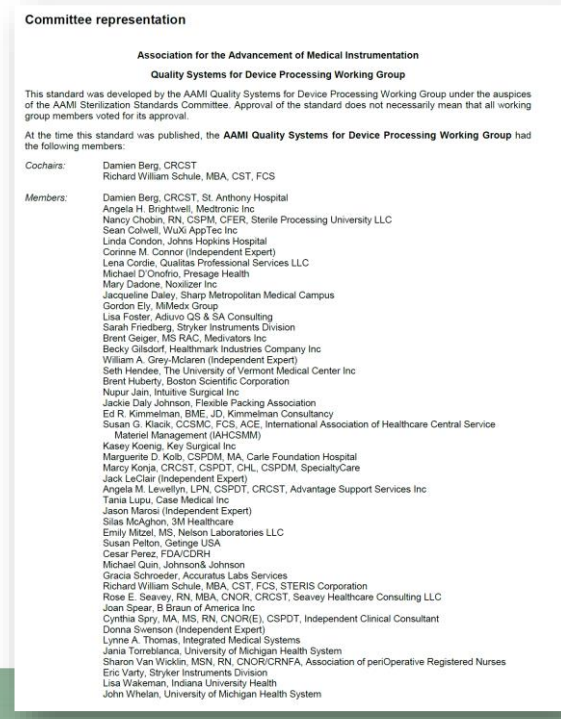
"This document is intended for **sterile processing personnel** and specifies a minimum requirement for a quality management system (QMS) in a health care organization *to effectively, efficiently, and consistently process medical devices to prevent adverse patient events and non-manufacturer related device failures*. *AAMI News, September 2017 Page 22*



Committee Representation

AAMI defines 4 categories of representation:

- Users
- Regulators
- Industry
- General Interest



Committee representation

Association for the Advancement of Medical Instrumentation

Quality Systems for Device Processing Working Group

This standard was developed by the AAMI Quality Systems for Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

At the time this standard was published, the **AAMI Quality Systems for Device Processing Working Group** had the following members:

Cochairs:
Damien Berg, CRCST
Richard William Schule, MBA, CST, FCS

Members:
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Linda Condon, Johns Hopkins Hospital
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Lena Cordie, Qualitas Professional Services LLC
Michael D'Onofrio, Presage Health
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Jacqueline Daley, Sharp Metropolitan Medical Campus
Gordon Ely, MiMedx Group
Lisa Foster, Adluvo QS & SA Consulting
Sarah Friedberg, Stryker Instruments Division
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Seth Hendee, The University of Vermont Medical Center Inc
Brent Huberty, Boston Scientific Corporation
Nupur Jain, Intuitive Surgical Inc
Jackie Daly Johnson, Flexible Packing Association
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Jack LeClair (Independent Expert)
Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services Inc
Tania Lupu, Case Medical Inc
Jason Marosi (Independent Expert)
Silas McAghon, 3M Healthcare
Emily Mitzel, MS, Nelson Laboratories LLC
Susan Pelton, Getinge USA
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Donna Swenson (Independent Expert)
Lynne A. Thomas, Integrated Medical Systems
Jania Torreblanca, University of Michigan Health System
Sharon Van Wicklin, MSN, RN, CNOR/CRNFA, Association of periOperative Registered Nurses
Eric Varty, Stryker Instruments Division
Lisa Wakeman, Indiana University Health
John Whelan, University of Michigan Health System

What is the Intended Purpose of ST90?

Provide Guidelines

Planning, documentation & implementation of processes, procedures & records

Create Structure

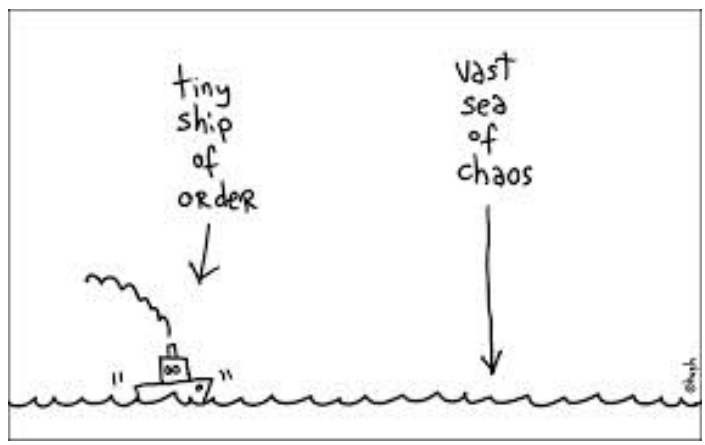
Culture, processes & methodology to achieve repeatable & reproducible results

Ensure Patient Safety

Consistent processing of medical devices to prevent adverse events & non-manufacturer related device failures

Quality Management Systems 101

What is a Quality Management System?



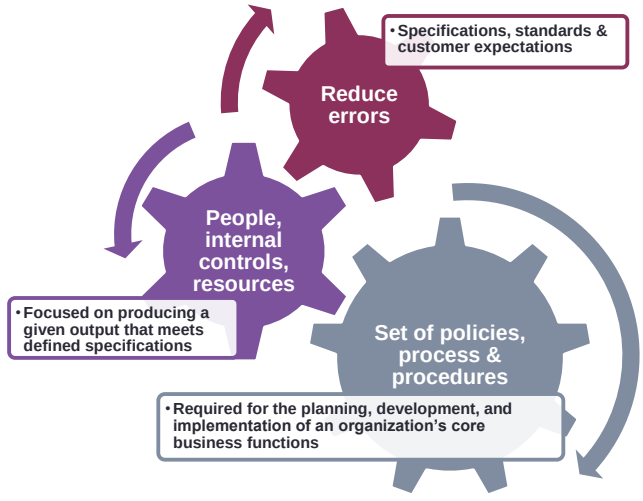
What is a Quality Management System?

A set or network of **defined processes** that **interact** throughout an organization to **achieve uniformity** of a product [service] in order to satisfy specific customer or user [facility] requirements

AND

That **coordinate** through **controlled** and **defined activities**, the continual **efficiency** and **effectiveness** of an organization, towards a mutual, **measurable** end.

What is a Quality Management System?



Incorporates 7 Principles of Quality Management

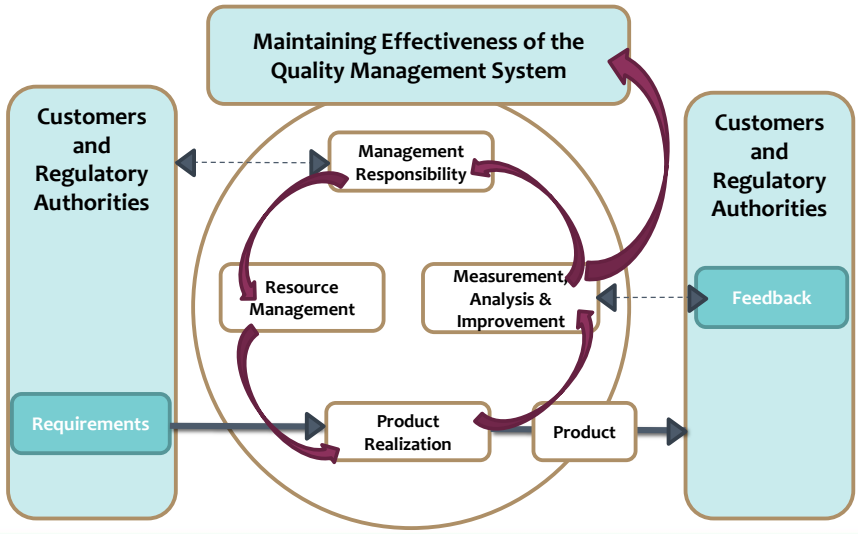
QMS Basics

- **Process Model**
- Plan-Do-Check-Act Cycle
- Overview of Sections in ST90

The Process Model in Concept

- An organization is a system of interlinked processes
- Key processes – those that lead to products and services – must be identified
- ST90 is geared to managing and improving the processes
- Methods to measure and control processes must be included

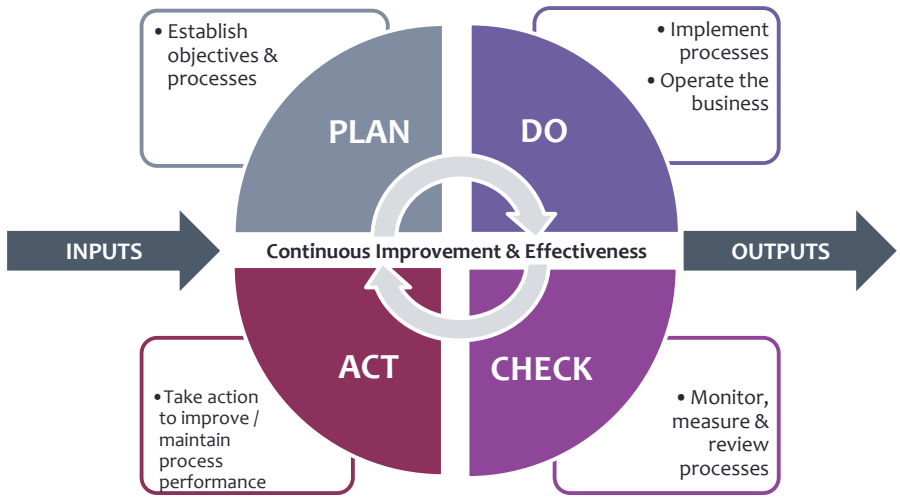
The Process Model in Illustration



QMS Basics

- Process Model
- **Plan-Do-Check-Act Cycle**
- Overview of Sections in ST90

The "Plan Do Check Act" Cycle



QMS Basics

- Process Model
- Plan-Do-Check-Act Cycle
- **Overview of Sections in ST90**

ST90 Standard – by Section

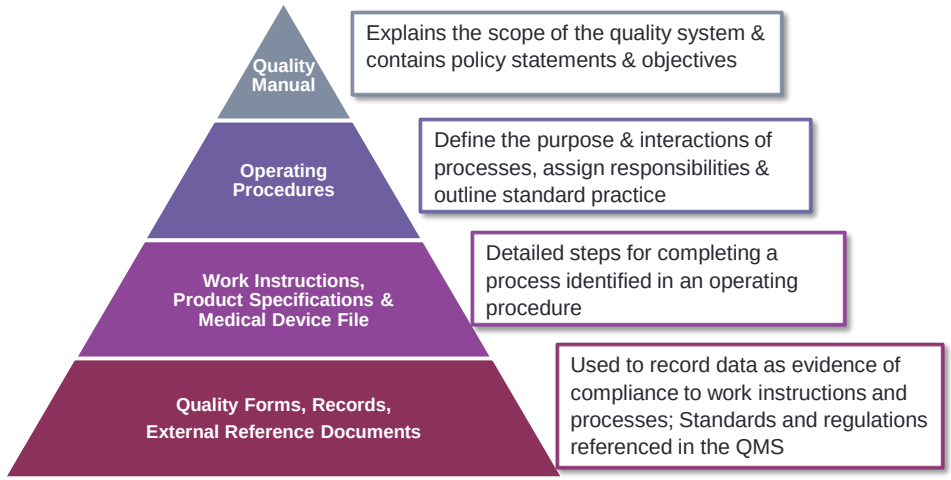
Clause*	Description
1 Scope	Defines the 'boundaries' of the standard Identifies what is included & excluded from the standard
2 Normative references	Lists other documents that are indispensable to the application of the standard
3 Definitions and abbreviations	Lists terms, abbreviations and their meanings as used in the context of the standard

ST90 Standard – Section 4

Clause	Description

4 Quality management system	Defines the minimum requirements for establishing a QMS
	• Look for the 'SHALL' statements
	
	Required documentation:
	• Quality policy
	• Quality objectives
	• Quality manual
	• Documented procedures
	  • required of the standard (6)
	  • required of the health care organization
	• Records
	
	Includes requirements for control of documents & records to prevent unauthorized use or revision

Documentation System



ST90 Standard – Section 5

Clause	Description
5 Management responsibility	Requires **top management** show evidence of a **commitment to the** development, implementation & maintenance of a **QMS** Top management needs to: • Create the department's quality policy & objectives • Conduct management reviews of the QMS • Provide any necessary resources • Ensure that all changes to the QMS are planned

CONFIDENCE starts at the TOP!

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Top Manager Confidence

- Drives a clear focus on department quality & productivity objectives
- Improves ability to accurately understand and consistently meet customer requirements
- Directs alignment of employees and processes to the same objectives

Middle Manager Confidence

- Reduces variability & increases consistency through standardization
- Enhances communication between management, employees, and departments
- Encourages clarity of responsibility, authority, and accountability

Frontline Staff Confidence

- Provides consistency to better perform daily activities
- Increases confidence that work meets quality standards & performance expectations
- Empowers employees to make process improvements when results are not meeting requirement

ST90 Standard – Section 6

Clause	Description
6 Resource management	Requires that adequate resources are determined and provided to implement and maintain a QMS and all of its processes • Human resources • Equipment • Competency, Education & Training • Infrastructure • Work Environment Requires management to be aware of both the QMS and the processes it supports

ST90 Standard – Section 7

Clause	Description
7 Product realization	Processes are required to design, test and produce safe & effective products Allows for repeatability & reproducibility Includes considerations for: • Planning for new devices, equipment, and materials • Determining customer requirements • Developing surgical sets and other device processing techniques • Purchasing • Processing and servicing • Control of monitoring and measuring equipment

ST90 Standard – Section 8

Clause	Description
8 Measurement, analysis, and improvement	Requires that outputs of the QMS be monitored & reviewed to determine the effectiveness of the processes and identify opportunities for improvement On-going review of the QMS creates a living system Ensures that objectives are consistent with organization's philosophy & expectations

Benefits of a QMS to SPD

Why is a QMS Important to SPD?

It defines **how** a **Sterile Processing Department** ***and*** **device processing areas** can **work together** to **meet requirements** of the customers and other stakeholders affected by their work.

How Do We Know that QMS Works?

STANDARDS
are created to
positively change
QUALITY

QUALITY
results from efforts to achieve uniformity through
STANDARDS

The Precedent Has Been Set

Standard
ISO 9001:2015 Quality management systems — Requirements
ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
IATF 16949:2016 Automotive quality management
ISO/FDIS 19443 Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

Benefits of a QMS to SPD

1 Patient Safety

"QUALITY MANAGEMENT IN HEALTH CARE - CONTRIBUTING TO PATIENT SAFETY AND EFFICIENCY OF BUSINESS OPERATION"

Nevenka Kovač, M.D.,M.B.A.,M.Sc.C.C.

Special hospital for orthopaedics, neurology and physical medicine and rehabilitation St. Catherine in Zabok, Republic of Croatia

- Healthcare Services - required to establish, develop and maintain a system for assuring and improving quality in healthcare
- Ensures efficient, effective, high quality & accessible health care across the entire Croatian territory
- QMS are equally important to the provision of cross-border healthcare

2 Efficiency

"IMPROVING EFFICIENCY AND VALUE IN HEALTH CARE: INTRODUCTION"

Health Services Research (HSR), 2008 Oct

- On average hospitals could increase outputs 26% by eliminating inefficiency
  - About 3% of inefficiency due to productivity loss associated with patient safety problems
  - Inefficiencies also due to unused resources (i.e. idle personnel)
- Two most frequent categories of operational failures: equipment/supplies and facility issues
  - Posed safety risks and diminished staff efficiency
- Prioritize quality improvements to increase safety & efficiency of hospitals

3 Culture of Quality

"ROADMAP TO A CULTURE OF QUALITY IMPROVEMENT"

National Association of County and City Health Officials (NACCHO)

- Drives the policies, practices, and processes used to accomplish an organization's work
- All employees (senior leadership to staff) incorporate Quality Improvement into daily work
  - continuous consideration for how processes can be improved becomes second nature
- Requires leadership commitment, employee empowerment, patient focus, teamwork, collaboration, and continuous process improvement

4 Financial

- **Cost Reduction** – especially in the areas of rework, patient safety costs, and damaged/lost medical devices and equipment
- **Error Reduction** – reduces amount of time and resources spend reprocessing instruments, rescheduling of cases due to unavailability of equipment, costs associated with hospital acquired infections and rehospitalization
- **Morale** – improvement in employee morale, which in turn reduces employee turnover, and therefore reduces the cost of hiring and training new employees

5 Business Growth

- **Patient Safety = Patient Satisfaction** – increased patient satisfaction can lead to increased market share, as existing patients recommend the organization to other patients
- **Improved Relations with Suppliers** – integration of mutually beneficial success leads to increased supplier loyalty and supplier controls
- **Access to Foreign Markets** – organizations with QMS certification receive more recognition and have more competitive potential in foreign markets (i.e. medical tourism)

The Risk-Based Approach

Risk-Based Approach

Consistent application of the risk-based approach leads to a risk-based culture focused on constant, sustainable progress rather than spending time in a reactive, corrective state.

Risk-Based Approach

- Integration of risk throughout all QMS, organizational, and departmental processes
- Direct correlation of application of risk-based approach to number of corrective and preventive actions needed
- Proactive and constant reduction of risk to prevent problems
- Scope of QMS activities is based on risk
- Controls required for QMS process are based on risk

Quality vs Risk

Quality	Risk
Achieve Objectives	Failure to Achieve Objectives
• Zero defects • Customer satisfaction • Control of process variance • Reliability • Security • Fit for purpose	• Defects • Customer dissatisfaction • Uncontrolled process variance • Product unreliability • Security breach • Lack of fitness for purpose

How Quality Systems Reduce Risk

Mitigates the Fear of Change

Status Quo

- Less effective
- Less competitive
- Less organized

Change

- More confident
- More stable
- More flexible

Why do we need to document processes?

How will we make changes?

What if I forget to follow a procedure?

Who can I ask for help?

How is this going to help me?

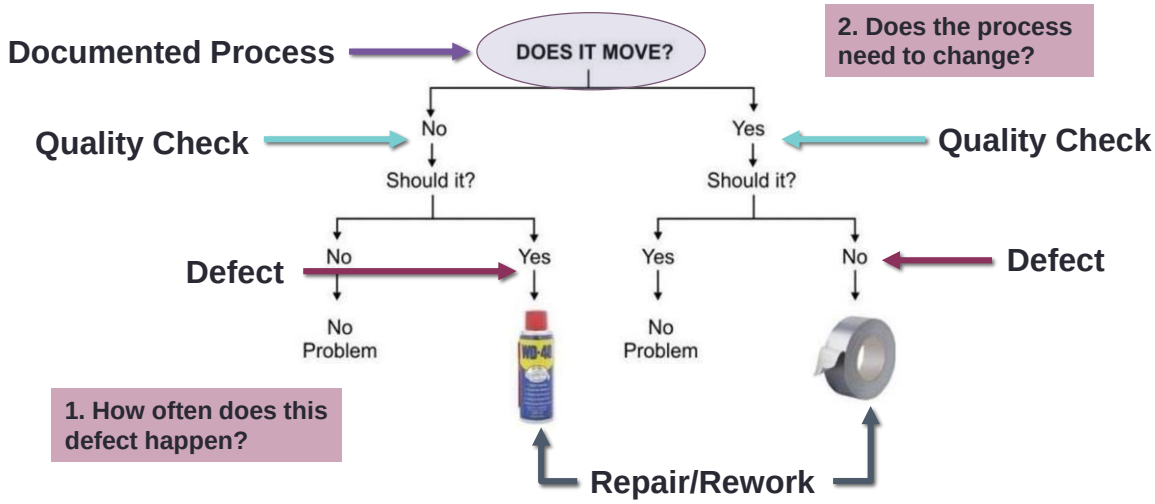
Provides a Documented System for Process Improvement

Structured approach | **Effective deployment** | **Improved control**

Reduces risk through:

- **CONSISTENCY**: Process are optimized when best practices are documented
- **REPEATABILITY**: Processes are not person-dependent; All employees can perform the work
- **EFFIENCY**: Activities are performed smoothly
- **ACCOUNTABILITY**: Responsibilities are clearly assigned

Measures Processes, Defects & Improvements



Risk #1: Lack of continuous improvement process

Result of Risk	Benefit of QMS to Mitigate Risk
Processes will stagnate	QMS involves discovering the deficiencies that exist in a process & continuously looking for ways to improve
Defective products will reach customer/patient	Reduction in defects due to measurement of process, identification of issues, implementation of improvements
Increase costs from repair, rework and redundant production time	Decrease waste, improve efficiency, increase output

Risk #2: Disengagement of Employees

Result of Risk	Benefit of QMS to Mitigate Risk
Decrease productivity	Employees are involved and engaged in processes from beginning to end
Increase in attrition	Increases morale by empowering employees to identify improvements and holding people at all levels accountable
Increased training & productivity costs	Involved and happy employees will leave less frequently, ensuring consistency of outputs and training

Risk #3: Lack of Customer Satisfaction Program

Result of Risk	Benefit of QMS to Mitigate Risk
Customer needs are not known or understood	Customer focus is one of the quality principles incorporated in a QMS, and ensures that management aligns organizational objectives with customer needs and expectations
Customers (i.e. surgeons, nurses, patients) will go elsewhere for the services they need	Quality objectives are determined by top management, performance to the objectives is measured and reviewed, and improvements made to ensure objectives are met

Risk #4: Lack of Document Control

Result of Risk	Benefit of QMS to Mitigate Risk
Hinders improvement	Controlled documents provide a formal starting point for process measurement and improvement
Inconsistency and unreliability of documentation leads to less confidence in processes & SPD	ST90 sets out requirements for the development, approval, control and periodic review of department procedures
Uncertainty about responsibility & accountability within SPD results in no standard methods or control	SPD operates according to proven best practices and guidelines from Joint Commission, AAMI, AORN & IAHCSMM

Risk #5: Competitive disadvantage

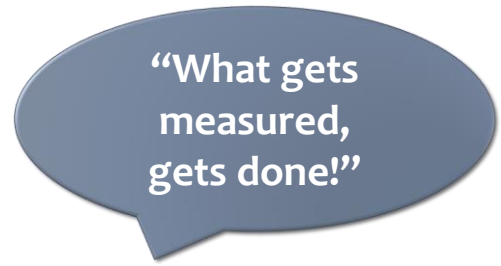
Result of Risk	Benefit of QMS to Mitigate Risk
Not seen as “best in class”	An organization committed to continually improving the quality of the services provided will attract medical professionals with the same commitment and dedication

“*Quality management system focused organizations seek out other quality management system focused organizations*”.

Measuring Quality in SPD

Principles of Effective Measurement

- Quality measurement is central to quality control and improvement
- Supplement measurements with resources & training to enable sterile processing technicians to achieve improvement



10 Principles of Effective Measurement

1 Define the purpose & use	2 Focus on the customer	3 Useful rather than easy	4 Participation	5 Proximity to activity
6 Indicators	7 Document plans for data	8 Simplicity of data & process	9 Periodic evaluations	10 Take action

Planning for Measurement and Data Collection

- Collect vs Generate data

- Ask the right questions
  - What is the goal?
  - What process or product is being monitored?
  - What question are you attempting to answer?

Types of Quality Measures

Classes of quality measures

1. Defect (deficiencies, failures)
2. Costs of poor quality
3. Product and process features
4. Customer needs
5. Customer behavior

$$\frac{\text{\# of Occurrences}}{\text{Opportunity for Occurrence}}$$

Measuring Quality - Decontamination

- ✓Point-of-use care of devices during the procedure
- ✓Preparation for transport to the device processing area
- ✓Availability of device IFUs for cleaning requirements
- ✓Education, training, & competency of staff performing the cleaning process and equipment operation
- ✓Verification process of cleaning or equipment performance
- ✓CAPAs related to decontamination process
- ✓5S the work area at the end of shift

Measuring Quality - Inspection & Assembly

- ✓Equipment assisted device inspection
- ✓Device performance verification testing
- ✓Supplier, Input, Processor, Output, Customer (SIPOC)
- ✓Education, training, and competency of staff performing the inspection & assembly process, and equipment operation
- ✓5S the work area at the end of shift

Measuring Quality - Packaging

- Education, training, and competency of staff performing the packaging process & equipment operation
- Packaging defects and/or failures
- 5S the work area at the end of shift

Measuring Quality - Sterilization & HLD

- Education, training, and competency of staff performing the sterilization & HLD process and equipment operation
- Sterilization failures
- 5S the work area at the end of shift

Measuring Quality - Storage & Distribution

- Education, training, and competency of staff performing the storage and distribution process and equipment operation
- 5S the work area at the end of shift

Creating a Culture of Quality

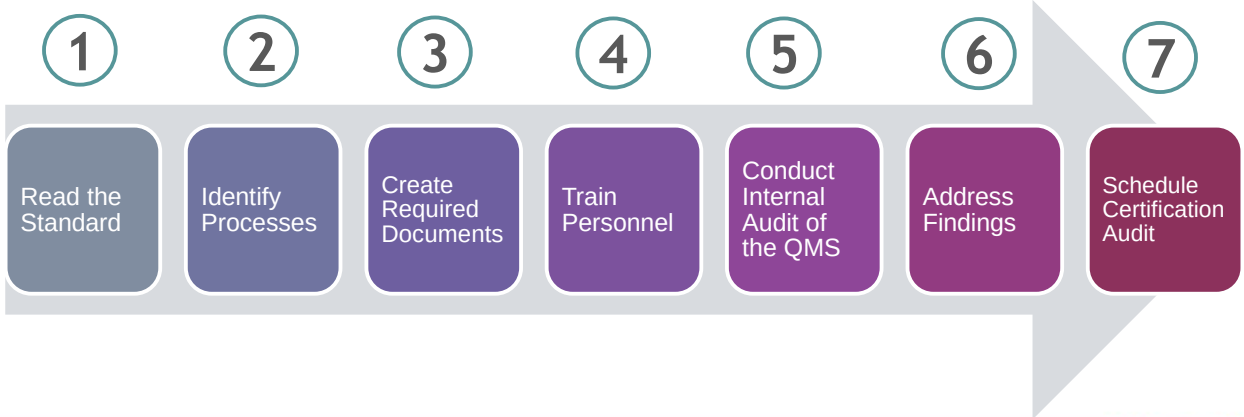
A Culture of Quality is Valuable

"A company with a highly developed culture of quality spends, on average, $350 million less annually fixing mistakes than a company with a poorly developed one."

Harvard Business Review
April 2014

Four Essentials to a Culture of Quality

Planning a QMS Implementation



Implementing a Sustainable QMS in SPD

Leadership	•Establish a vision and direction for the organization •Establish trust •Equip and empower employees
Engage & Educate	•Enable participation in continual improvement through open discussion of problems & constraints •Evaluate individual performance & enable learning and knowledge sharing
Process Approach	•Identify all SPD processes & manage activities as processes •Measure the capability of activities •Determine sequence & interaction of processes
Improvement	•Empower people to make improvements •Measure improvement consistently •Celebrate improvements
Informed Decisions	•Ensure the accessibility of accurate and reliable data •Use appropriate methods to analyze data & make decisions based on analysis •Balance data analysis with practical experience
Customer Focus	•Align organizational objectives with customer needs and expectations •Meet customer requirements & manage customer relationships •Measure customer satisfaction

Summary & Conclusion

- QMS provide organizations with numerous advantages over their competitors
- Well developed & maintained QMS positively contribute to achieving goals, improving patient safety & trust, and improving overall results & performance
- Quality has two key performance impacts on an organization:
  - ✓costs
  - ✓revenue

Summary & Conclusion

Internal advantages

- Gains an organization obtains within its processes
  - greater employee satisfaction
  - increased employee and process efficiency
  - reduced operating costs
  - increased revenue

External advantages

- Gains in relation to other organizations
  - more competitive marketing position
  - status as a more desirable employer
  - visibility of the organization's emphasis on quality & patient safety

American Society for Quality (ASQ)

www.asq.org

Quality Improvement Associate (CQIA)

Manager of Quality Organizational Excellence (CMQ/OE)

Quality Auditor (CQA)

What are You Doing To Improve?

10 Things Your Organization Can Do Now to Improve Reprocessing

This top 10 list emerged from the presentations, audience discussions, and follow-up input to AAMI. It is intended to be inspiring, and serve as a refresher on some of the basics. It does not take the place of standards, regulations, or internal policies, nor is it intended to suggest a standard of care. While some priority items from the summit will take time to address, we want everyone to know that there are at least 10 things that an organization can begin to do immediately, without waiting for other actions, such as long-term standards and research.

1. ***The basics:*** Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturers' written instructions for use (IFU). For more information go to www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm.
2. ***The right tools:*** Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
3. ***Create a multidisciplinary committee:*** To review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.
4. ***Share lessons learned:*** Remind senior management and safety officers that it costs a lot less to "do it right the first time." Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.
5. ***Written procedures:*** Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA's MedWatch program.

10 Things Your Organization Can Do Now to Improve Reprocessing

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6. ***Standards matter:*** Know the current standards, recommended practices, and IFU.
7. ***Purchasing:*** Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.
8. ***Separate and standardize functions and locations:*** Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.
9. ***Training:*** Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.
10. ***Assessment:*** Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. See References and go to: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.

AAMI Publications

Corrective and Preventive Action (CAPA)

- Implementation
- Controlling non-conforming products

Management Responsibility

Quality Audits

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References

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- Bauer, J.E., Duffy, G.L., Westcott, R.T., - The Quality Improvement Handbook, 2nd Edition, 242 pages. ASQ Quality Press, Milwaukee, WI 2006. Purchase from www.asq.org for $105.

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Questions