



World Federation for
Hospital Sterilisation Sciences

DGSV

Deutsche Gesellschaft für
Sterilgutversorgung e.V.

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WORLD CONFERENCE
CENTER FOR
ISO 13485 Quality Systems as a
Method of Reducing Risk in
Sterile Processing

- **Benefits that a quality system will bring to a sterile processing department**
- **Basics of a risk-based approach**
- **How quality systems reduce risk**
- **Key steps to implementing a sustainable quality management system in sterile processing**
- **Importance of creating a culture of quality**
- **How to measure quality in a sterile processing department**

1

Patient Safety

- Fewer hospital acquired infections due to processing
- Increased patient & doctor confidence

2

Efficiency

- Achieve greater consistency in processing activities
- Effective training tool

3

Culture of Quality

- Common core values, principles & behaviors
- Increased teamwork

4

Financial

- Reduced operational costs & expensive mistakes

5

Business Growth

- Competitive advantage
- Transparency of quality measures throughout organization

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)

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**

Risk in ISO 13485:2016

- Greater emphasis on risk management and risk-based decision making throughout all processes
 - Safety and performance
 - Compliance with regulatory requirements
 - 2003 version: “think” about risk during Product Realization
 - 2016 version: “apply” risk to all QMS processes including outsourced processes

Quality

Achieve Objectives

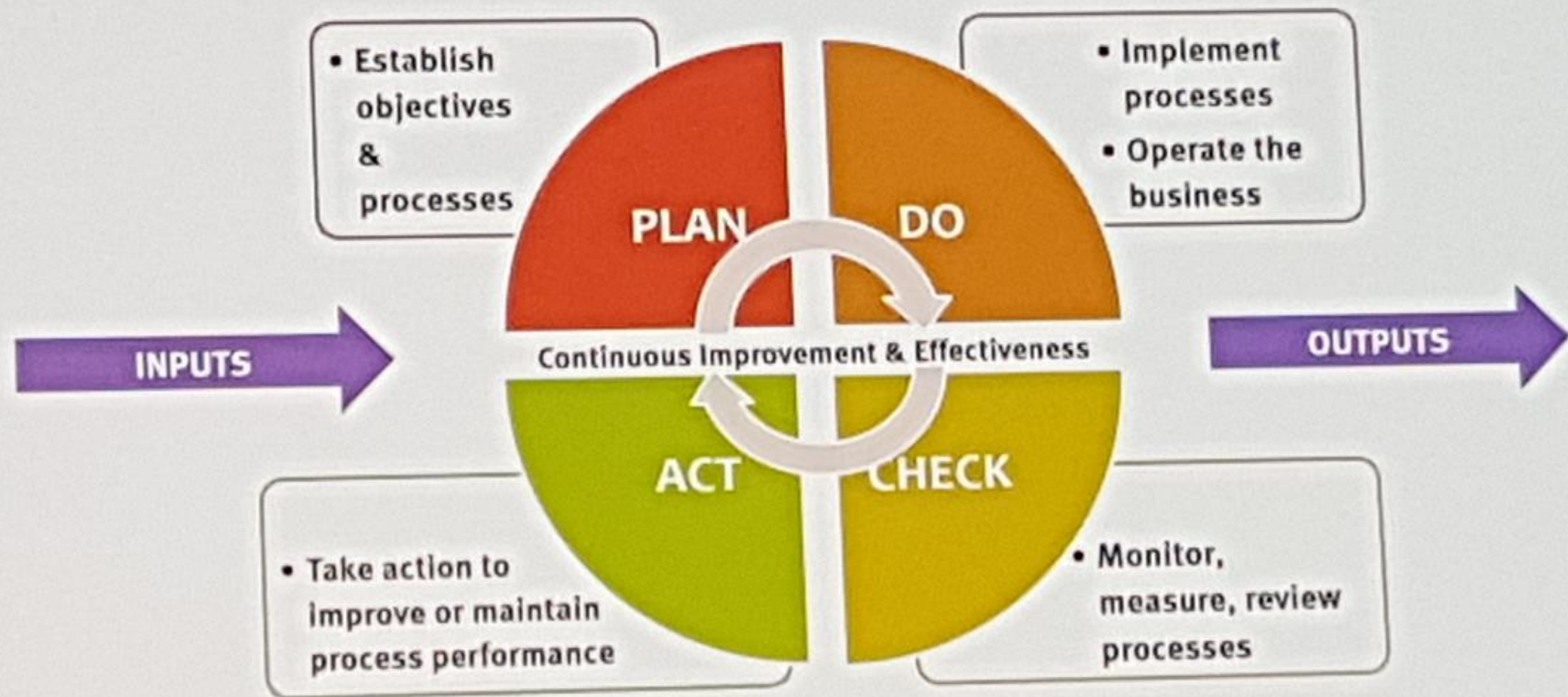
- Zero defects
- Customer satisfaction
- Control of process variance
- Reliability
- Security
- Fit for purpose

Risk

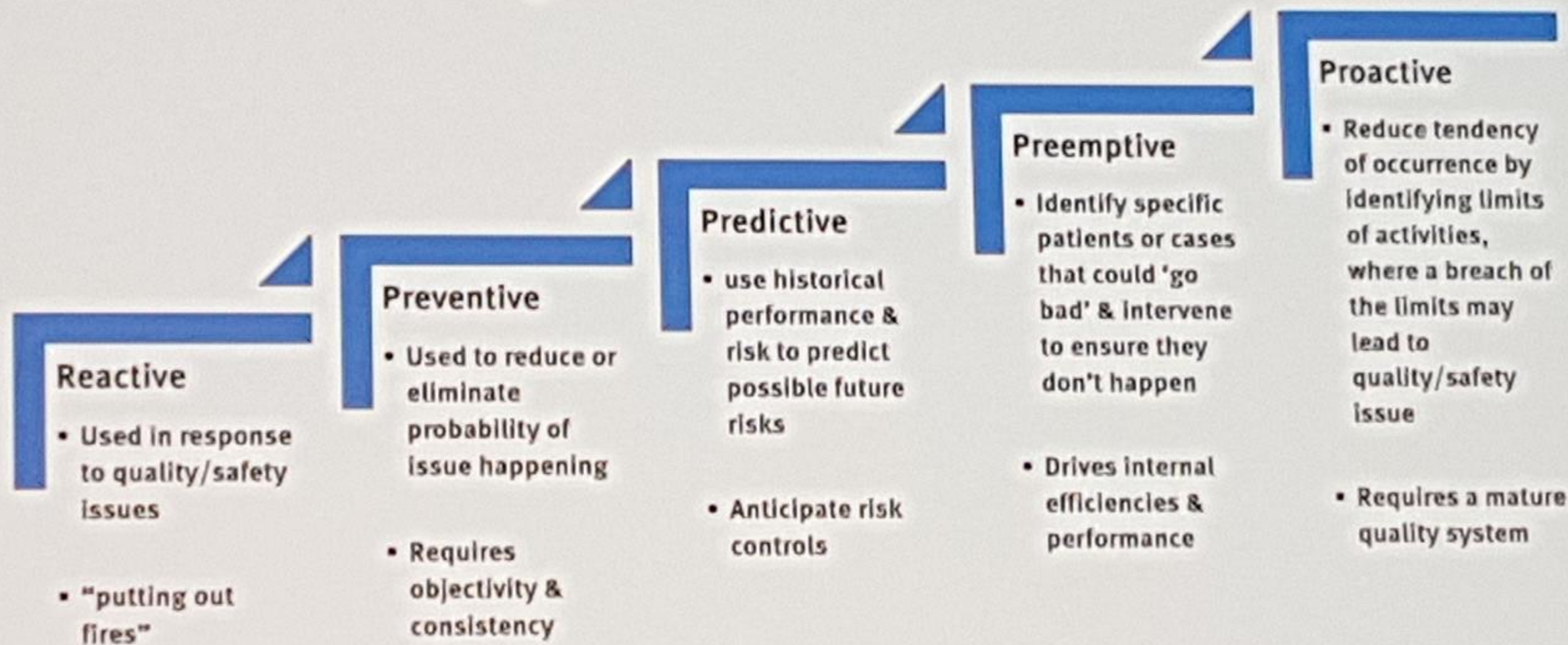
Failure to Achieve Objectives

- Defects
- Customer dissatisfaction
- Uncontrolled process variance
- Product unreliability
- Security breach
- Lack of fitness for purpose

The "Plan Do Check Act" Cycle



5 Types of Risk Management



IMPLEMENTING A SUSTAINABLE QUALITY SYSTEM

2017
18TH WORLD STERILIZATION CONGRESS

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Scope of ISO 13485:2016

- Requirements applicable to organizations regardless of size and regardless of type, except where explicitly stated
- Requirements specified for medical devices apply equally to associated services
- Required processes that are applicable to, but not performed by, the organization are the responsibility of the organization and must be accounted for by monitoring, maintaining and controlling the processes

Plan

- Engage leadership
- Identify quality team
- Define quality objectives
- Identify processes & interactions

Do

- Create documentation
- Apply risk to processes
- Train personnel on quality & quality processes
- Implement processes &

Check

- Monitor, measure & review processes & CSSD performance against objectives
- Conduct internal audits

Act

- Improve or maintain process performance
- Implement corrective & preventive actions

- **Quality management systems provide organizations with numerous advantages over their competitors**
- **Well developed & maintained quality management systems will positively contribute to achieving goals, improving patient safety & trust, and improving overall results & performance**
- **Quality affects two key aspects on an organization:**
 - impact on costs
 - impact on revenue

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
 - easier access to the global market
 - visibility of the organization's emphasis on quality & patient safety in foreign markets

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“Quality in Everything”