Nonconformity and risk management on product

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INTRODUCTION

The main objective of each sterilization service:

- Provide compliant medical device
- Ensure that the device has undergone compliant reprocessing according to legal and normative requirements

→ To ensure patient safety

A nonconformity can occur!

The sterilization service must:

- Respond to the nonconformity to control and correct it (corrective actions)
- Conduct periodic analyses to find and eliminate the causes of the nonconformity
- Seek and implement necessary actions to prevent the nonconformity from recurring
- Evaluate nonconformities and control associated risks

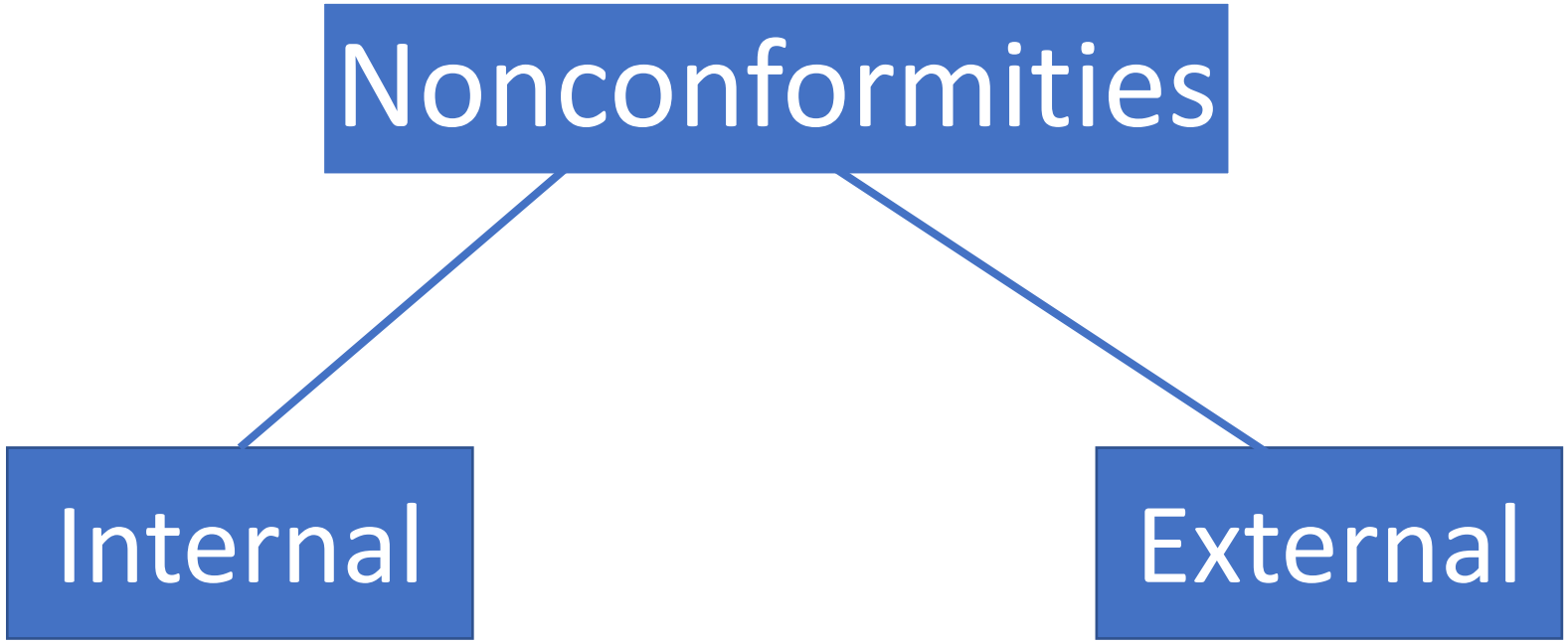
- The Nonconformity Management Process is required
- Risk analysis is a must

What are its characteristics according to the requirements ISO 9001, ISO 13485, ISO 14971, and Swiss best practices?

DEFINITION OF NON CONFORMITY

According to ISO 9000:
«Non-fulfillment of a requirement»

According to the requirements of the QMS ISO 9001, nonconformities are due to:
Non-compliance with product technical requirements (materials, characteristics, performance, etc.)
Processes (errors in quantities, delivery delays, improper use of equipment, human error due to lack of training)


Nonconformities
Internal
External

LEGAL AN NORMATIVE REMINDER

Medical Devices Ordinance
Art. 71 Maintenance
Art. 72 Reprocessing

ISO 9001: Quality management systems - Requirements
Chapter 10.2 Nonconformity and corrective action
Chapter 10.3 Continual improvement

ISO 13485: Quality management systems - Requirements
8.2 Monitoring and measurement
8.2.2 Handling of complaints
8.2.3 Reporting to regulatory authorities

SWISS BEST PRACTICE

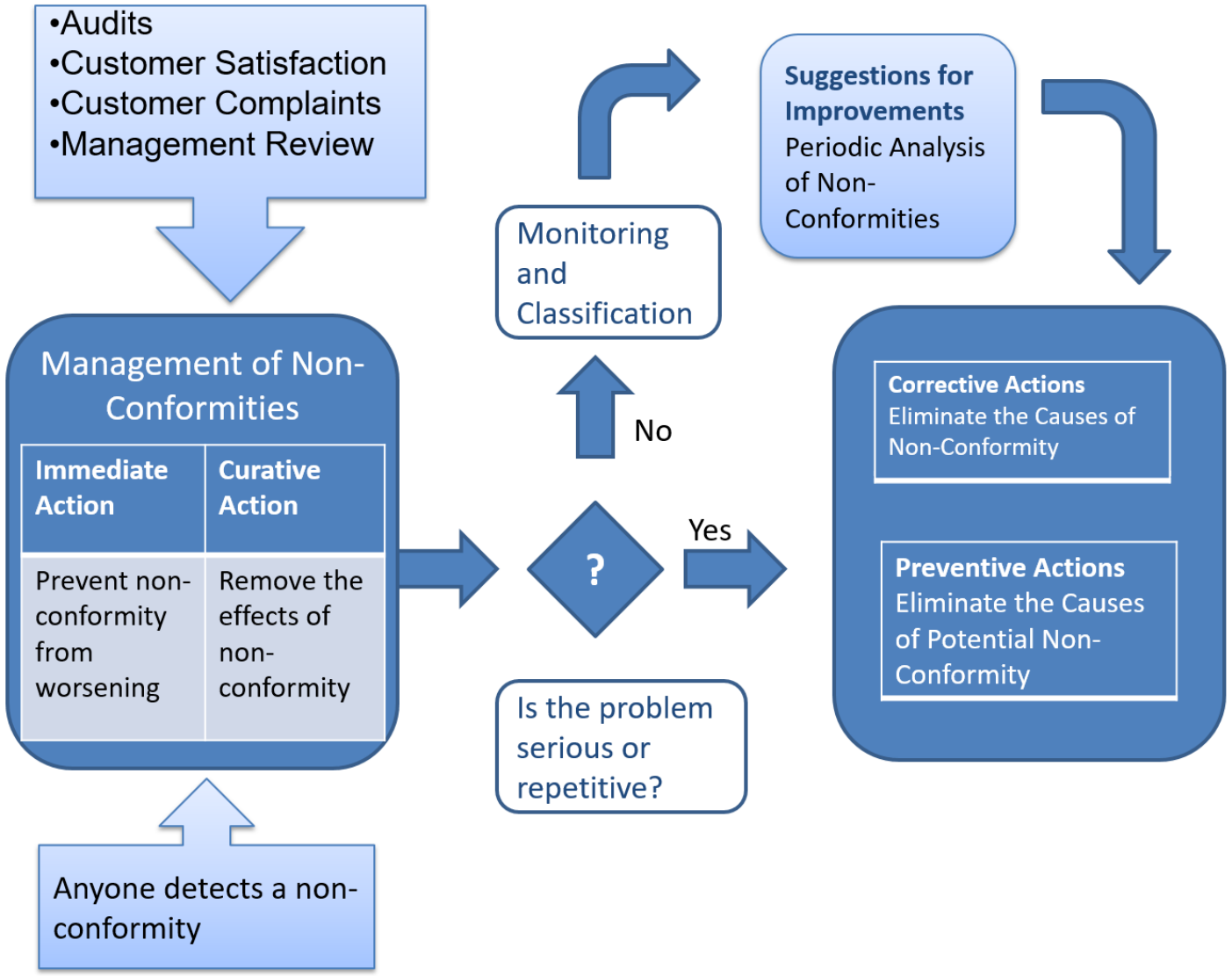
Chapter 3: QMS

Chapter 3.4: Risk Management

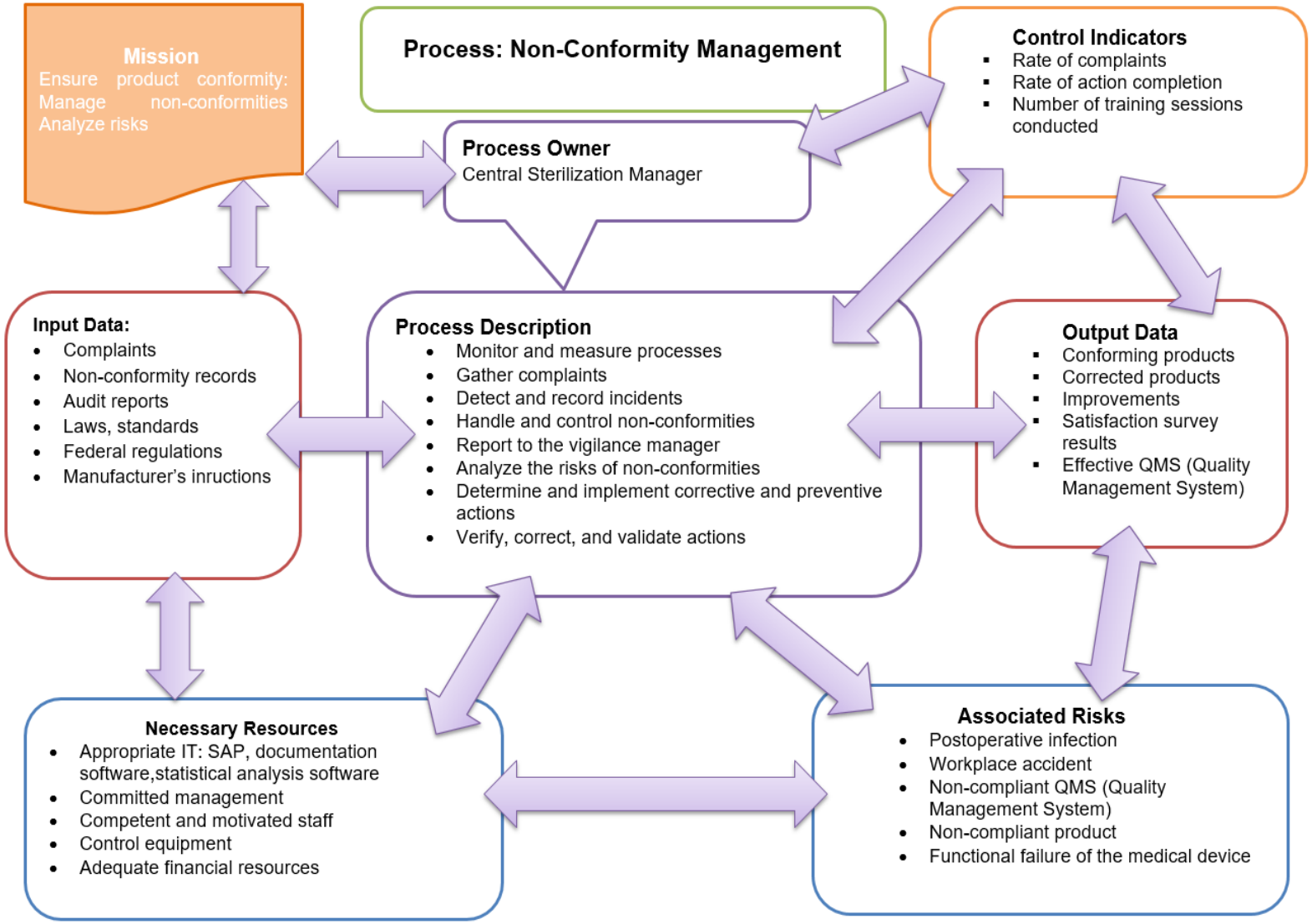
Chapter 8: Control of monitoring and measurement devices

Chapter 8.1: Monitoring and measurements
Chapter 3.4: Risk Management
Chapter 8.2: Improvement actions
Chapter 8.3: Control of non-conforming products

NC MANAGEMENT DIAGRAM

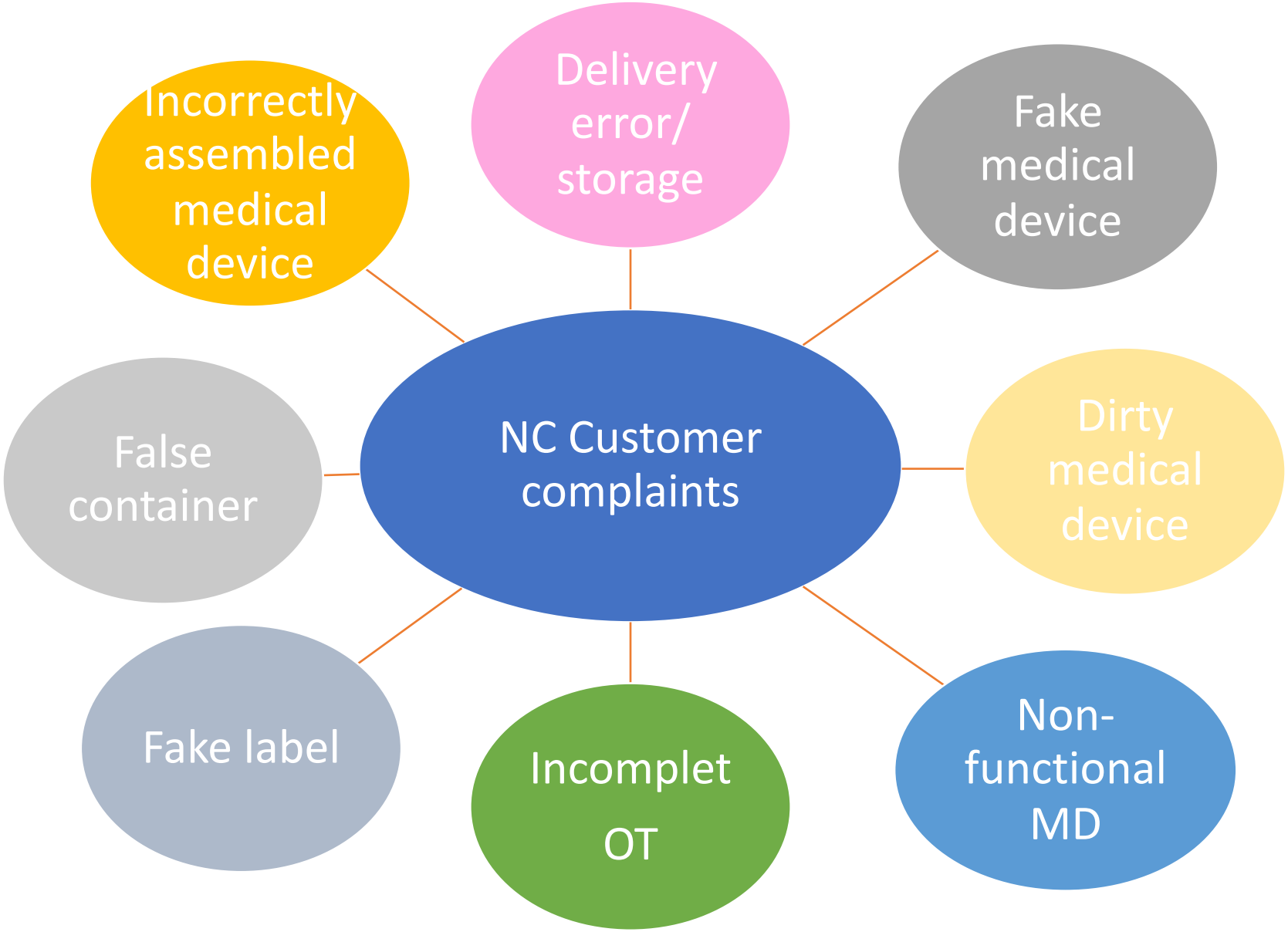


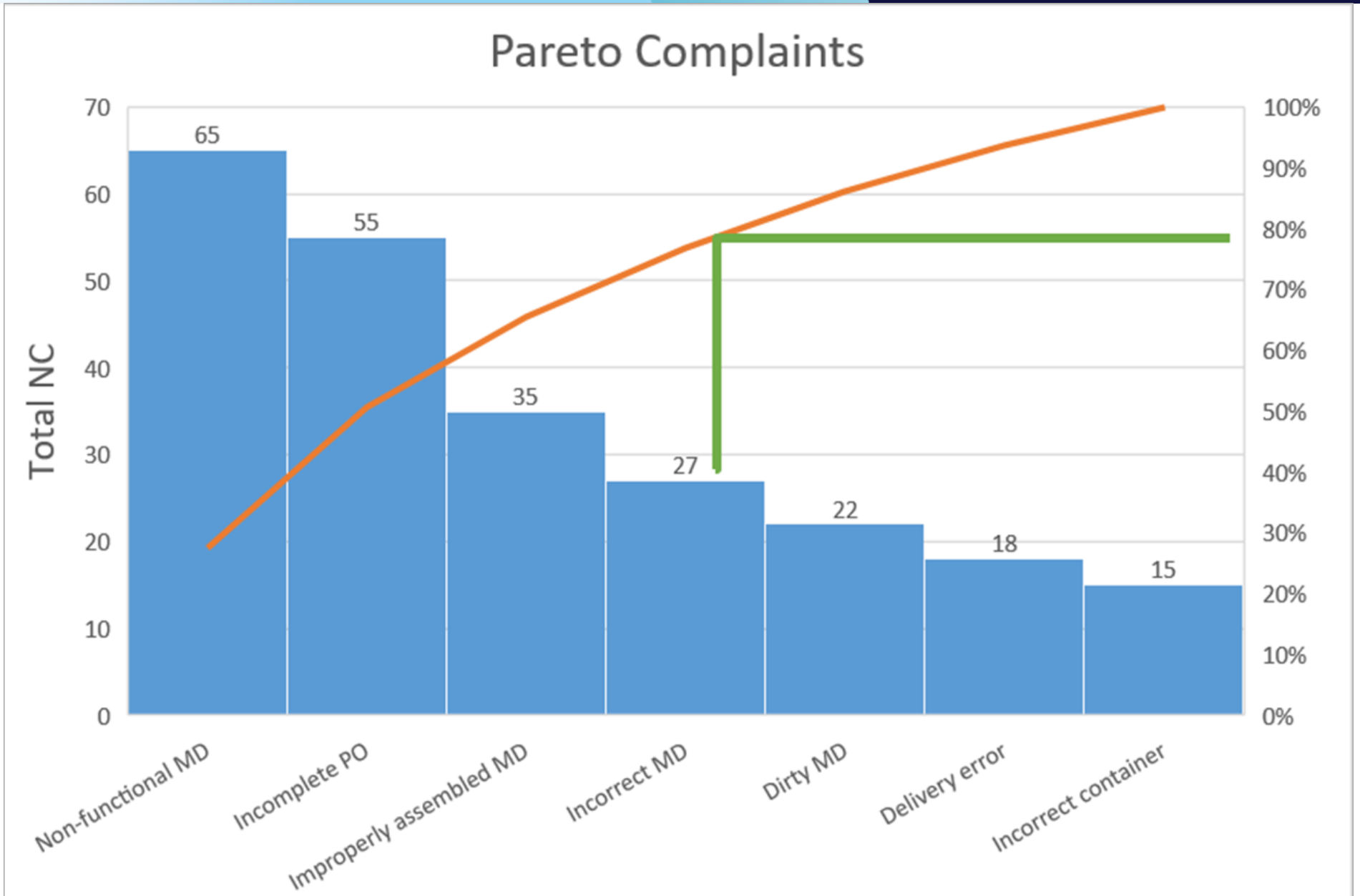
NONCONFORMITY MANAGEMENT PROCESS

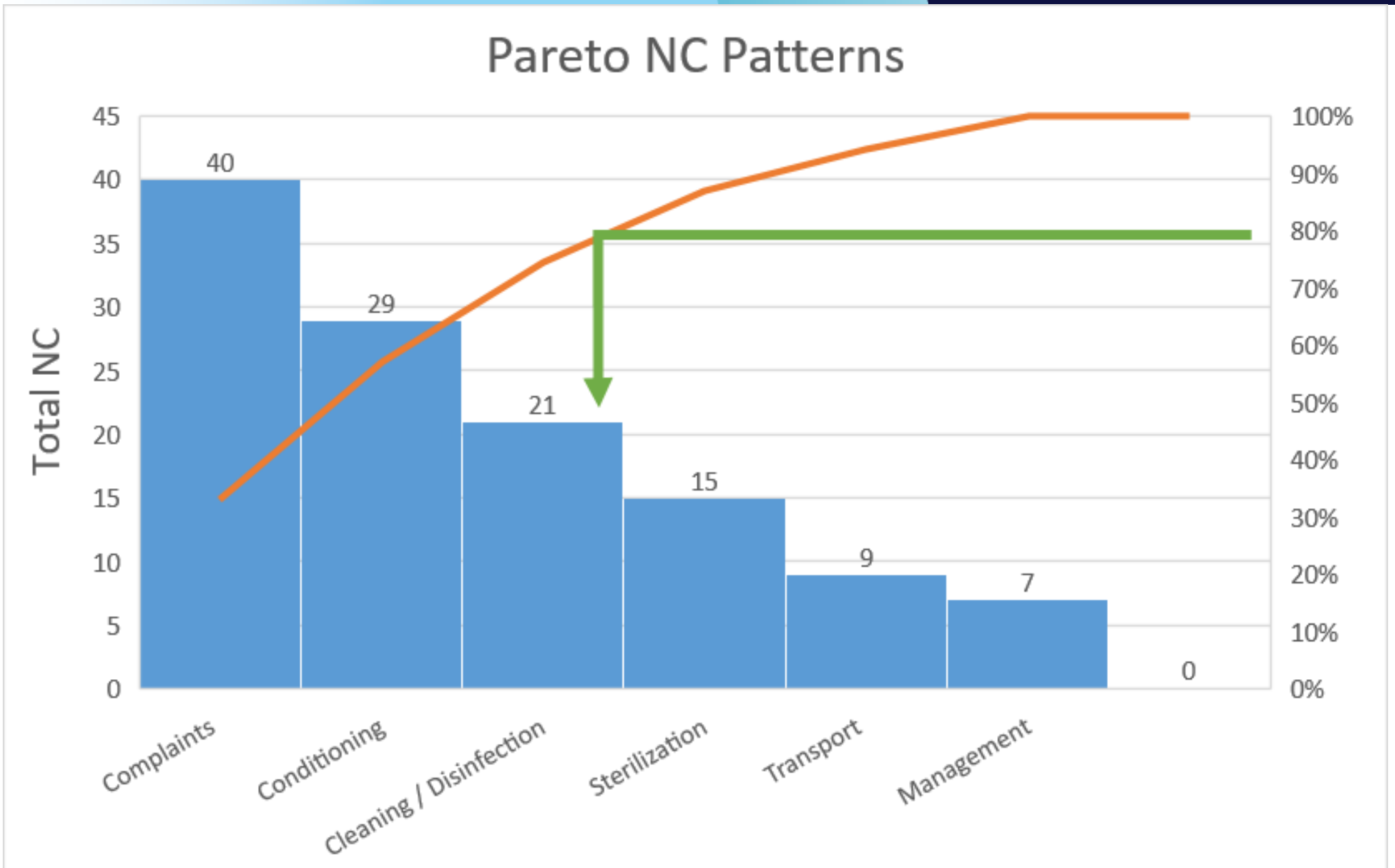


PRACTICAL CASE: STERILIZATION DEPARTEMENT UNIVERSITY HOSPITAL OF BERNE

- Identify nonconformities
- Determine risks
- Corrective actions: Determine the causes of the nonconformity
- Preventive actions: Determine the causes of potential nonconformity
- Implement and verify the effectiveness of corrective and preventive actions


NC Customer complaints
Incorrectly assembled medical device
Delivery error/ storage
Fake medical device
False container
Dirty medical device
Fake label
Incomplet OT
Non-functional MD

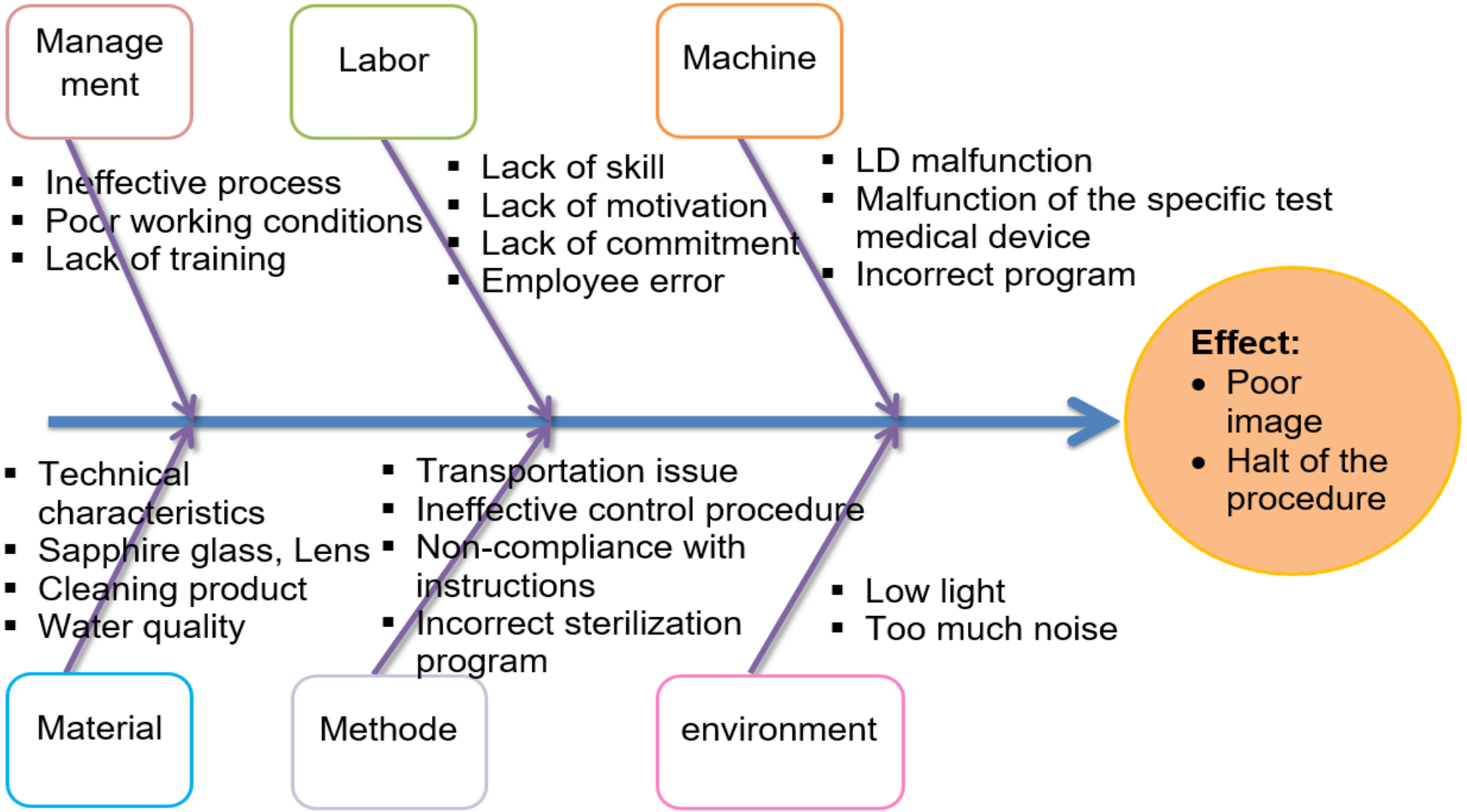

Pareto Complaints
Total NC
70
60
50
40
30
20
10
0
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
65
55
35
27
22
18
15
Non-functional MD
Incomplete PO
Improperly assembled MD
Incorrect MD
Dirty MD
Delivery error
Incorrect container


Pareto NC Patterns
Total NC
45
40
35
30
25
20
15
10
5
0
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
40
29
21
15
9
7
0
Complaints
Conditioning
Cleaning / Disinfection
Sterilization
Transport
Management

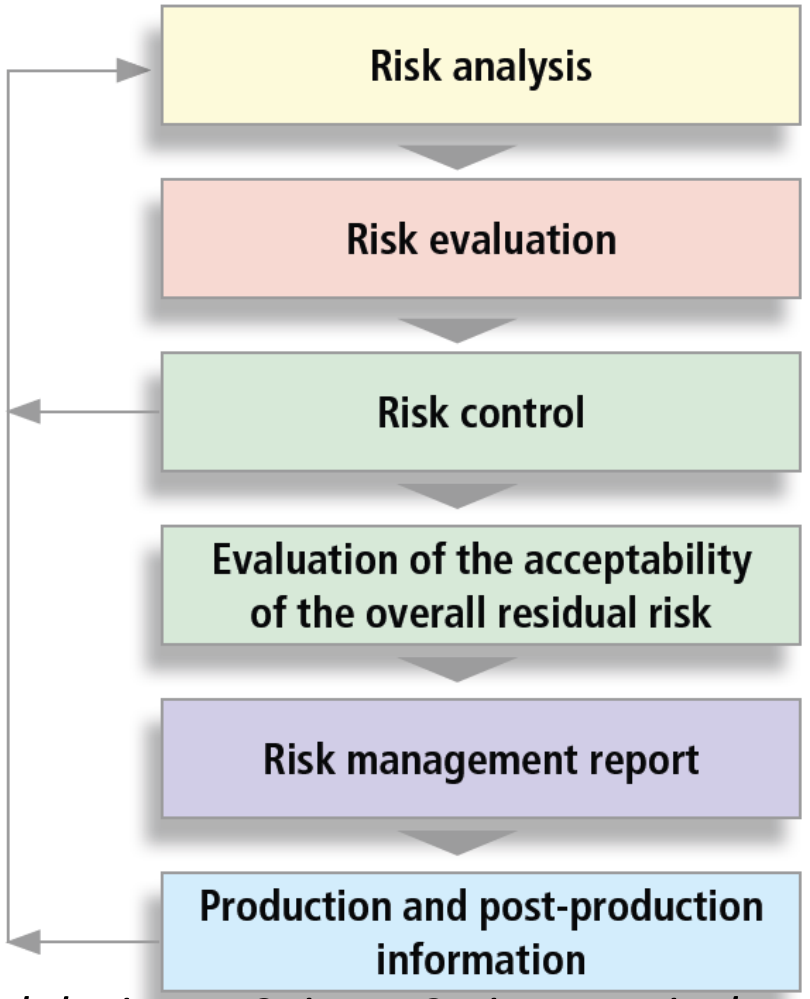
QUALITY TOOLS

Tools	Identify the NC	Determine Immediate and Curative Actions	Determine Corrective and Preventive Actions	Implement Solutions	Verify Solutions
Histogram	√		√		√
SWOT	√				√
Ishikawa		√	√		
Brainstorming	√	√	√	√	
7 MUDA		√	√	√	
5 Why		√	√		
Pareto	√			√	√
FMECA		√	√	√	
Prioritization Matrix				√	
Quality Circles	√	√	√	√	√

ISHIKAWA


Manage ment
Labor
Machine
Ineffective process
Poor working conditions
Lack of training
Lack of skill
Lack of motivation
Lack of commitment
Employee error
LD malfunction
Malfunction of the specific test medical device
Incorrect program
Effect:
Poor image
Halt of the procedure
Technical characteristics
Sapphire glass, Lens
Cleaning product
Water quality
Transportation issue
Ineffective control procedure
Non-compliance with instructions
Incorrect sterilization program
Low light
Too much noise
Material
Methode
environment

RISK ANALYSIS ACCORDING TO ISO 14971



Reference: Riskmanagement for medical devices – Snitem-Cetim practical guide, 2018

RISK ANALYSIS ACCORDING TO BPR

FMECA Method

Risk criticality = severity x frequency x detectability

- Critical nonconformity
- Major nonconformity
- Minor nonconformity

HANDLING COMPLIANTS IS A DAILY TASK

Regarding NC due to complaints:

- Handle immediately case by case
- Determine risks
- Determine corrective and preventive actions

RISK ANALYSIS ACCORDING TO BPR

G x F \ Détectabilité	1	2	3	4
1	1	2	3	4
2				
3				
4				
5				
6				
8				
9				
10				
12				
15	15	30	45	60

The Criticality Scale Can Be Interpreted as Follows:

- **Criticality from 1 to 10:** The risk can be accepted, minor corrections can be made, and the situation can be addressed within 2 weeks following the event.
- **Criticality from 12 to 27:** The risk must be reduced, corrective actions must be taken, and the situation must be addressed within the week following the event.
- **Criticality from 30 to 60:** The risk must be reduced, major corrections must be made, and the situation must be addressed immediately or within 48 hours.

RISK ANALYSIS ACCORDING TO BPR

G x F \ Détectabilité	1	2	3	4
1	1	2	3	4
2	2	4	6	8
3	3	6	9	12
4	4	8	12	16
5	5	10	15	20
6	6	12	18	24
8	8	16	24	32
9	9	18	27	36
10	10	20	30	40
12	12	24	36	48
15	15	30	45	60

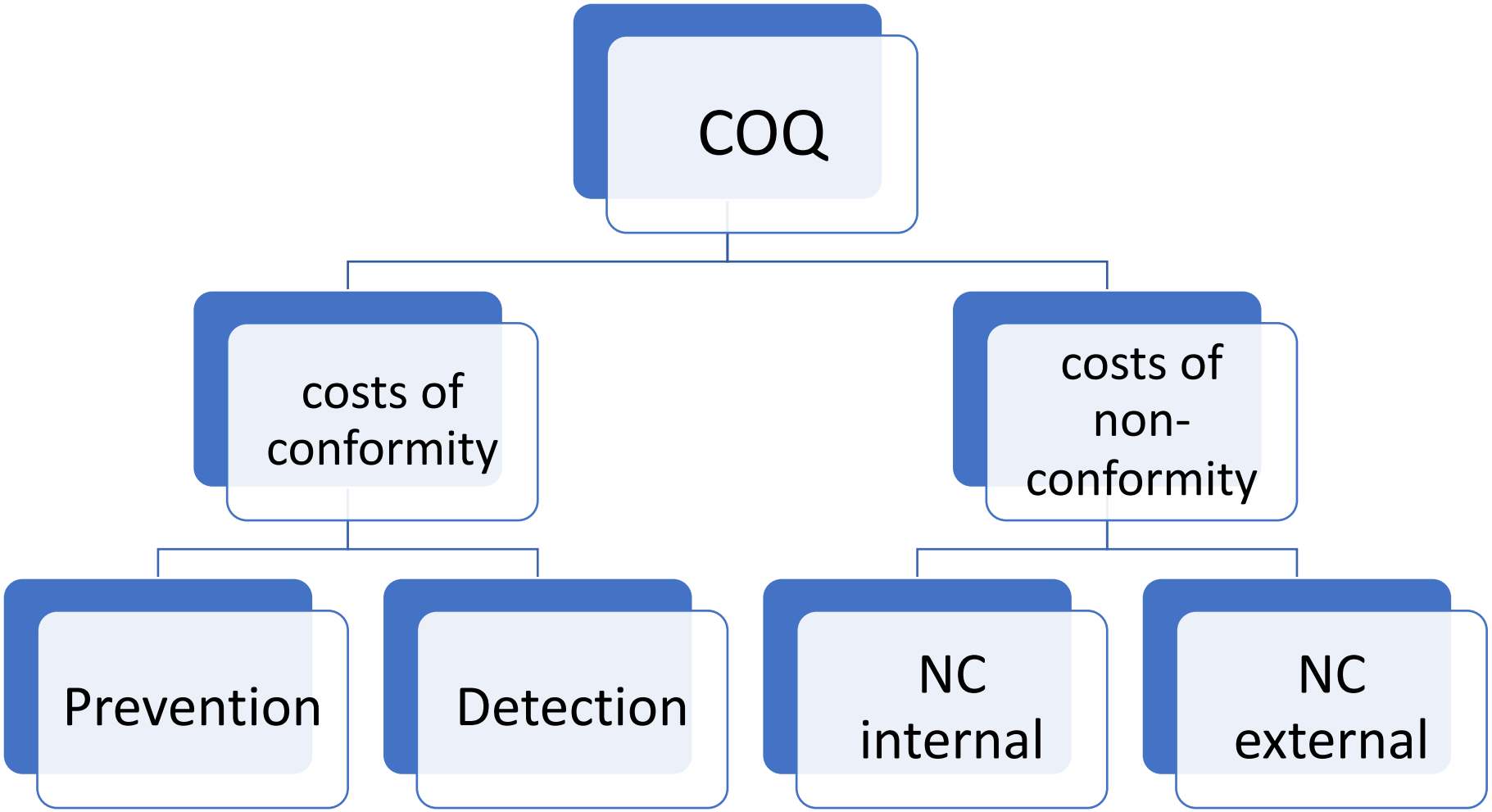
False container

Incorrectly mounted DMx

Non-functional DMx

Incomplete set

COST OF OBTAINING QUALITY (COQ)



COST OF OBTAINING QUALITY (COQ)

The Costs of Obtaining Quality (COQ)	
Prevention	▪ Analyses for improvements ▪ Training, audits ▪ Quality management
Control	▪ Labor ▪ Control equipment ▪ Training ▪ Laboratory tests
External Non-Conformities	▪ Handling of complaints ▪ Repair ▪ Product replacement
Internal Non-conformities	▪ MUDA (waste) ▪ Repair ▪ Product destruction ▪ Study of additional improvements

CONCLUSION

- Collaboration with operating rooms is essential for reprocessing nonconformities.
- Employee involvement
- Records of the nature of the nonconformity and all subsequent actions taken, including any obtained exemptions, must be kept.
- Control of monitoring and measurement equipment.
- Controls, responsibilities and associated authorities for handling NCs must be defined in a procedure.
- Quality Manager, System manager, and staff: competent, motivated.
- The Quality Manager and System Manager must master all reprocessing operations of medical devices.

CONCLUSION

- The nonconformity management process is a mandatory element of the management review.
- Conduct a quality audit to make this process effective.
- Nonconformity management is a crucial parameter for demonstrating the effectiveness of processes and the Quality Management System (QMS).
- Interfaces must be precisely delineated.

Thank you for your attention