



# 19<sup>TH</sup> WORLD STERILIZATION CONGRESS 2018

**XIII INTERNATIONAL STERILIZATION CONGRESS AND HOSPITAL DISINFECTION**

OCTOBER 31 TO NOVEMBER 3  
2018 WORLD TRADE CENTER  
MEXICO CITY

## SCIENTIFIC PROGRAM



# WORLDWIDE HARMONIZED PRACTICES ,

**Dr C.DENIS, WFHSS President & P.DESTREZ**





# **WORLDWIDE HARMONIZED PRACTICES , AN INACCESSIBLE CHALLENGE ?**

**Dr C.DENIS, WFHSS President & P.DESTREZ**



# Introduction

- Where are our practices coming from?
- Why different practices?
- Is it an issue?
- Solution?





# Role of CSSD in the hospital

- ▶ Cornerstone in the strategy of infection control
- ▶ CSSD = support of all the health care activities of a facility
- ▶ Surgery stops within 48h when CSSD is not running
- ▶ CSSD is the heart of hospital





# Our role

- Provide Reusable Medical Devices (RMD) clean and sterile (or disinfected)
- Repeatedly
- For 100% of the reprocessed ReMD

To guarantee the patient's safety



# Our objectives

- Put patient first
- Do everything not to add an extra risk to the surgery or care





# Are these objectives shared worldwide?

Yes!

## WHO Global Patient Safety Challenge





We should have the same practices...





# What is the current situation?

- The practices are varied
- Some examples:
  - Parametric release and qualification vs use of BI/CI (2 worlds)
  - Steam sterilisation program (134°C 3/18 min, 132°C...)
  - Qualified Washer disinfectors vs manual cleaning
  - Packing materials
  - Expiry time
  - .....





# Why?

**Non harmonized  
practices**

non harmonized  
guidelines  
(or absence of  
guidelines)

non harmonized  
education programs



# Why different guidelines?

- Local conditions:
  - involvement of Health Care Authorities,
  - Awareness of the issue of decontamination (prevention's policy)
  - Finances
- Habits
- Authors/orientation



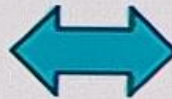
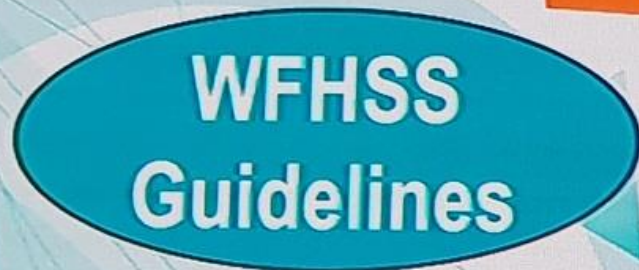


# Is it an issue?

- Yes it is!
- The lack of harmonization :
  - slows down the global progress
  - prevents to speak with one voice

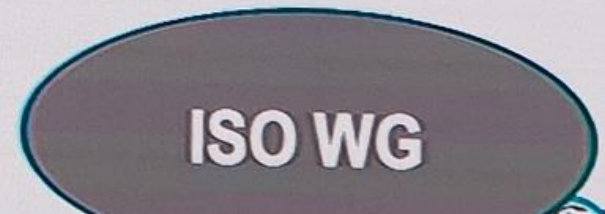


# Our solution WFHSS



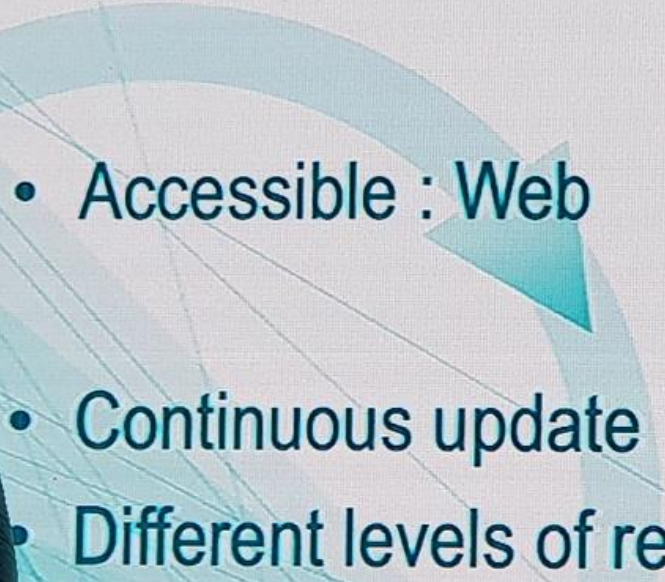
**Collaboration with industry:**

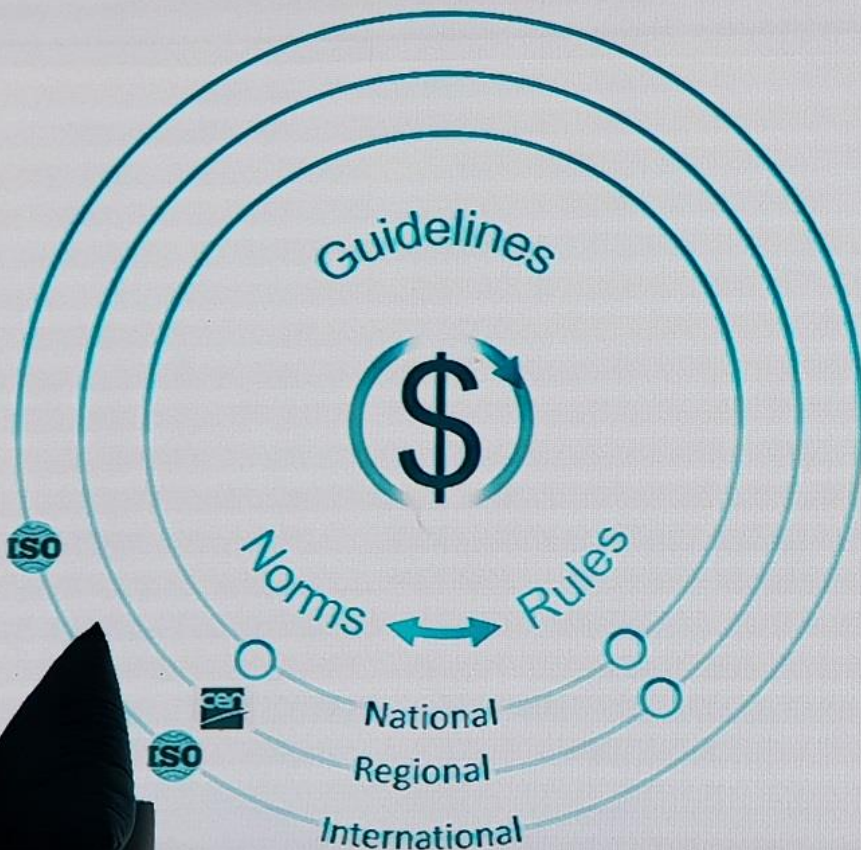
- education program
- IFU





# Harmonized guidelines

- Written by experts and users
  - Available for free
  - Accessible : Web
  - Continuous update
  - Different levels of reading
- 



## \$ Norms (or standards)

- Consensus & Voluntary
- Quality Management and risk
- Operator and patient safety

## \$ Norms (sterilization)

- Sterilizers & washer-disinfectors
- Packaging & Indicators (BI, CI)
- MD manufacturer reprocessing instructions

## \$ Norms (challenges)

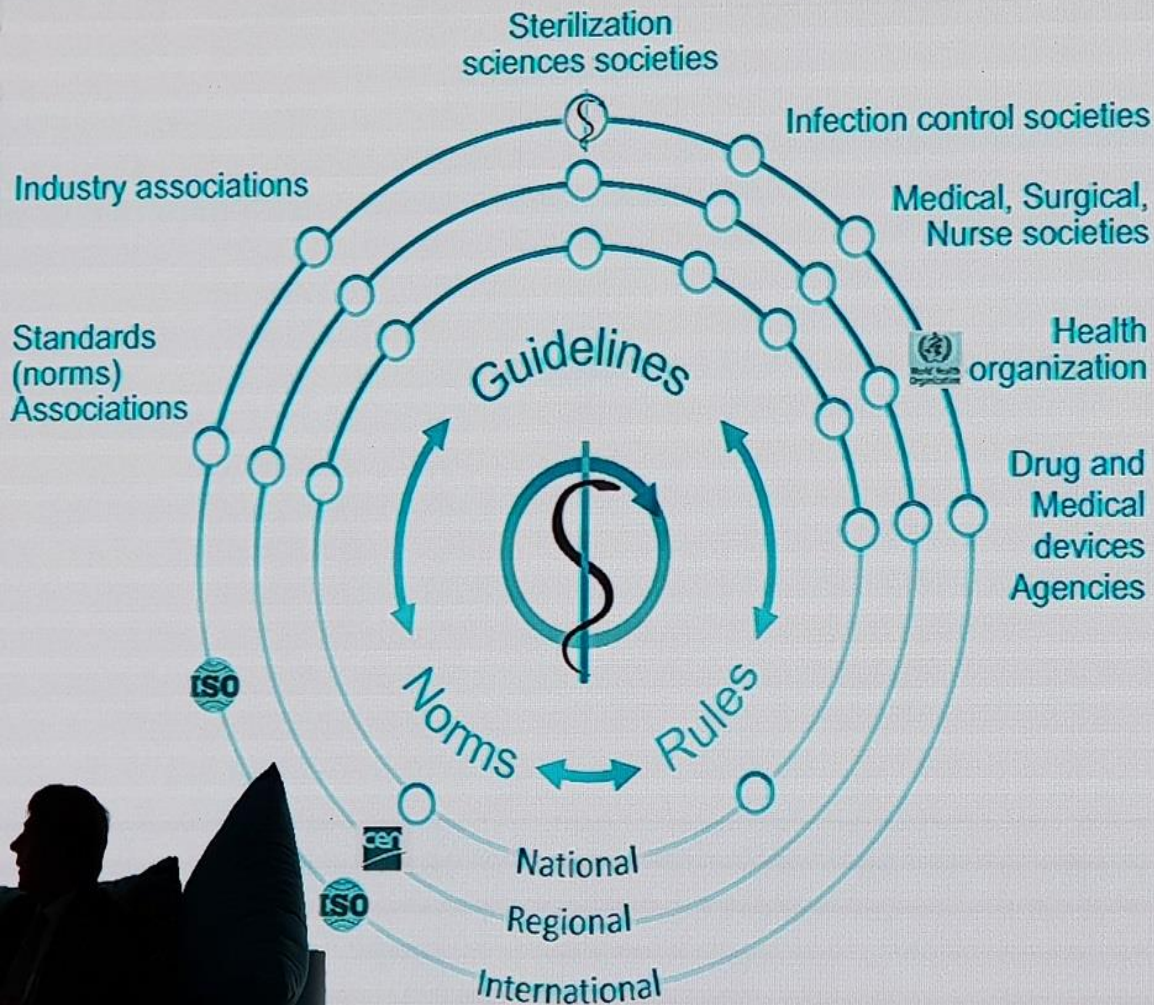
- Limits of consensus
- For experts

Worldwide harmonized practices, an inaccessible challenge ?





# Guidelines



Worldwide harmonized practices, an inaccessible challenge ?

Conseil Supérieur de la Santé

Department of Health

INSPQ INSTITUT NATIONAL DE SANTÉ PUBLIQUE DU QUÉBEC



HCAI

Hf  
Institute for Health Care Quality and Patient Safety Division



DAS



swissmedic

ROBERT KOCH INSTITUT

BfArM

DGSV



CDC



AAMI



FDA



EFSA



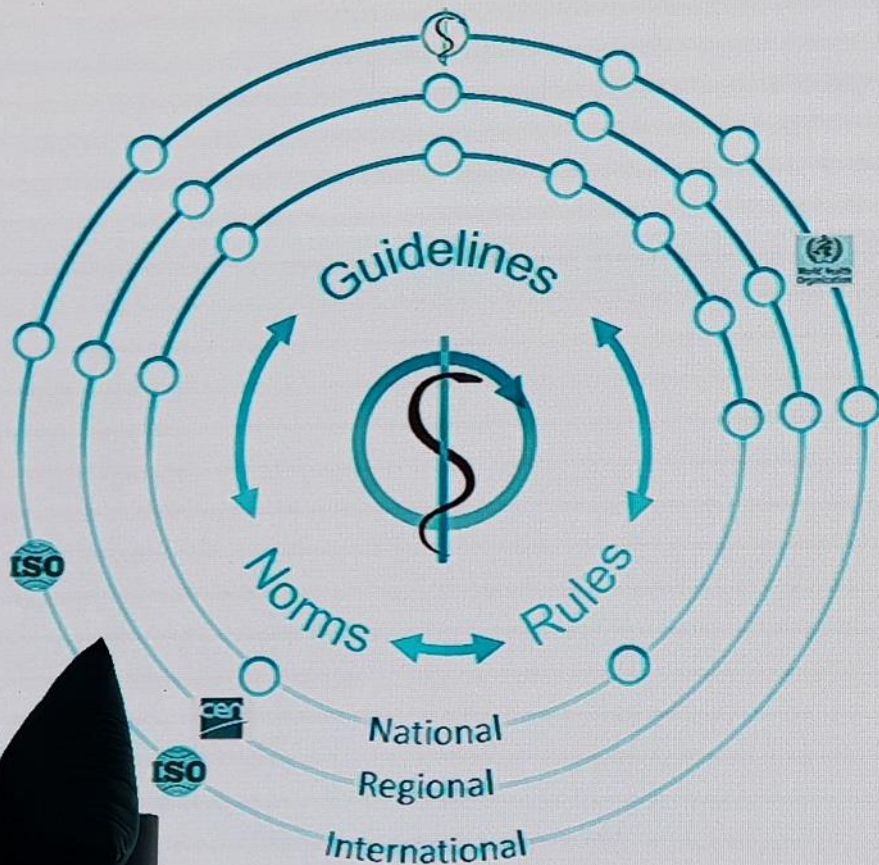
afnor



EUROPEAN UNION







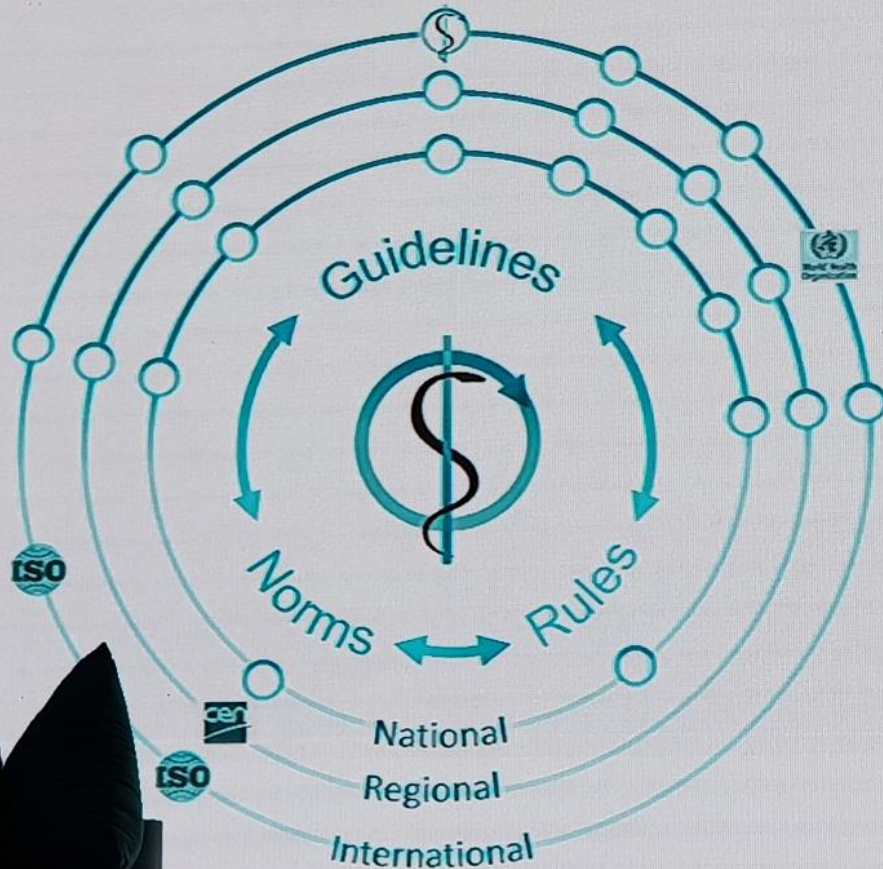
## Guidelines - contents

- Regulation/organization/norms
- Medical Devices (Spaulding)
- Operations (point of use → storage)
- Validations & Routine controls
- Maintenance
- Quality & Risk Management




Worldwide harmonized practices, an inaccessible challenge ?









## Guidelines - strengths

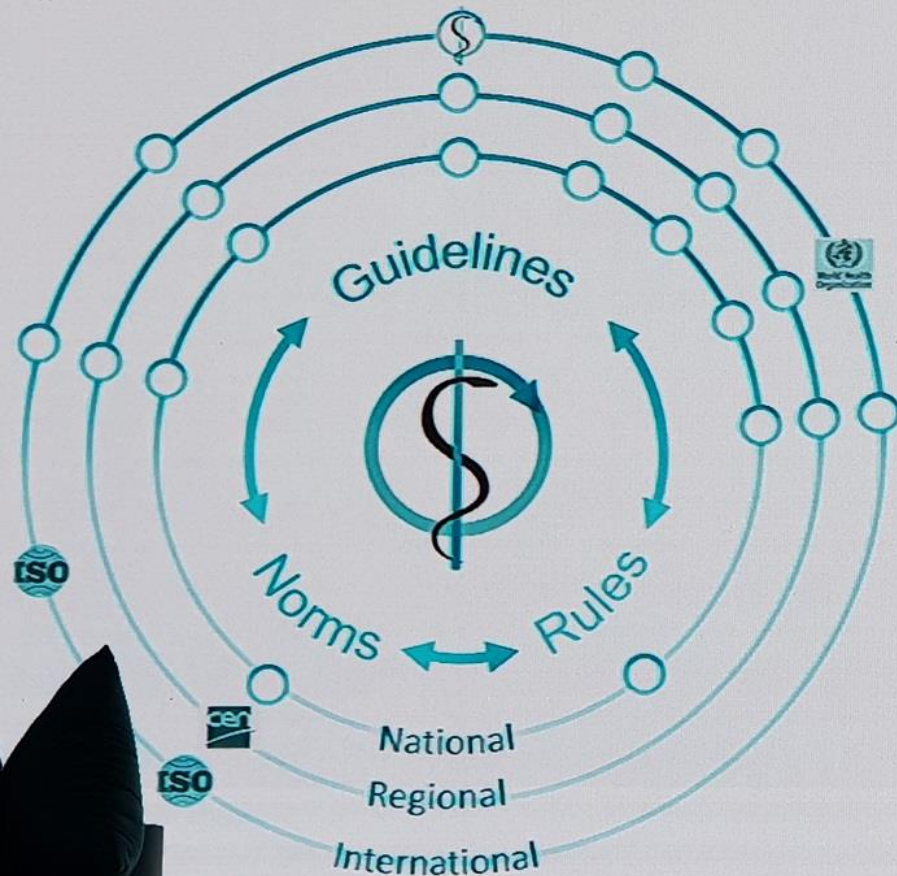
-  Adapted to local context & history
-  Interpretation of norms and rules
-  Practical & Educative

## Opportunities for improvement






-  Innovation / updates
-  Scientific society

Worldwide harmonized practices, an inaccessible challenge ?





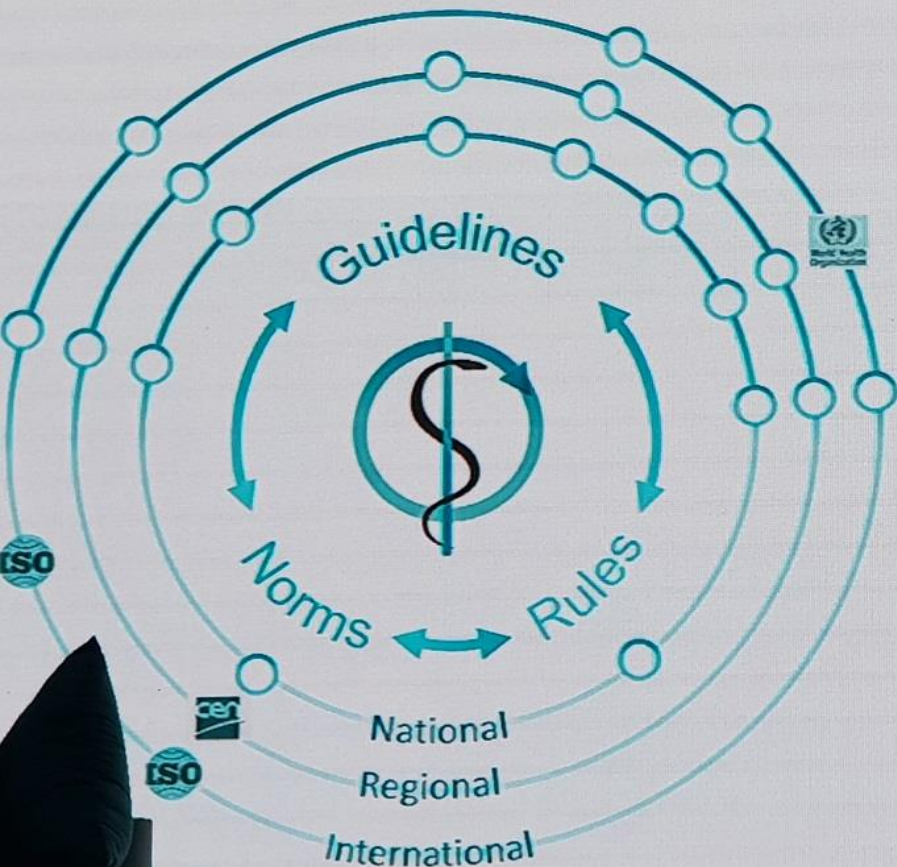
## CSSD dynamics

-  Surgical technologies
-  CSSD technologies (fast BI, cleaning tests etc..)
-  Results / Efficiency
-  Quality, Traceability, Risk
-  Norms and rules

Worldwide harmonized practices, an inaccessible challenge ?

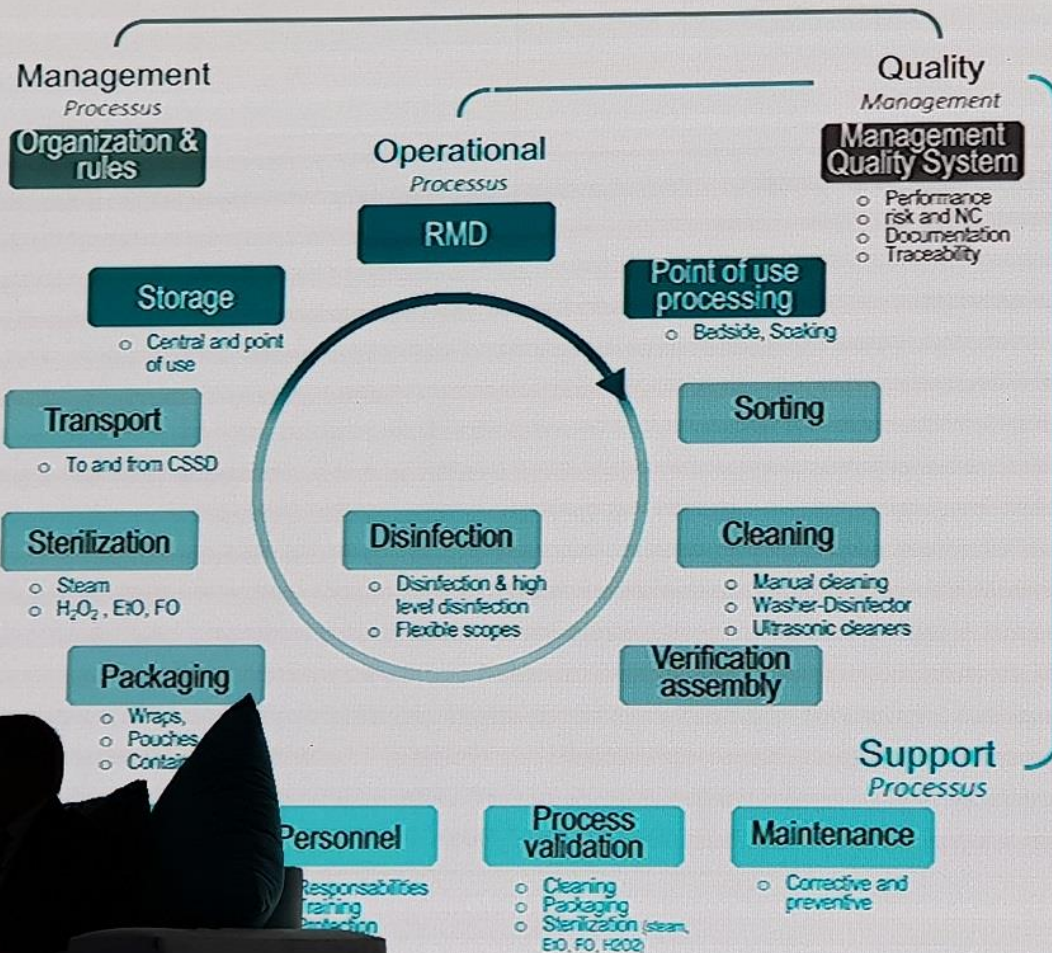






## WFHSS Guidelines

- Scientific
- Innovation → updates
- Strategic priorities
- Dialogue with industry, ISO, countries
- Education (train the trainer)

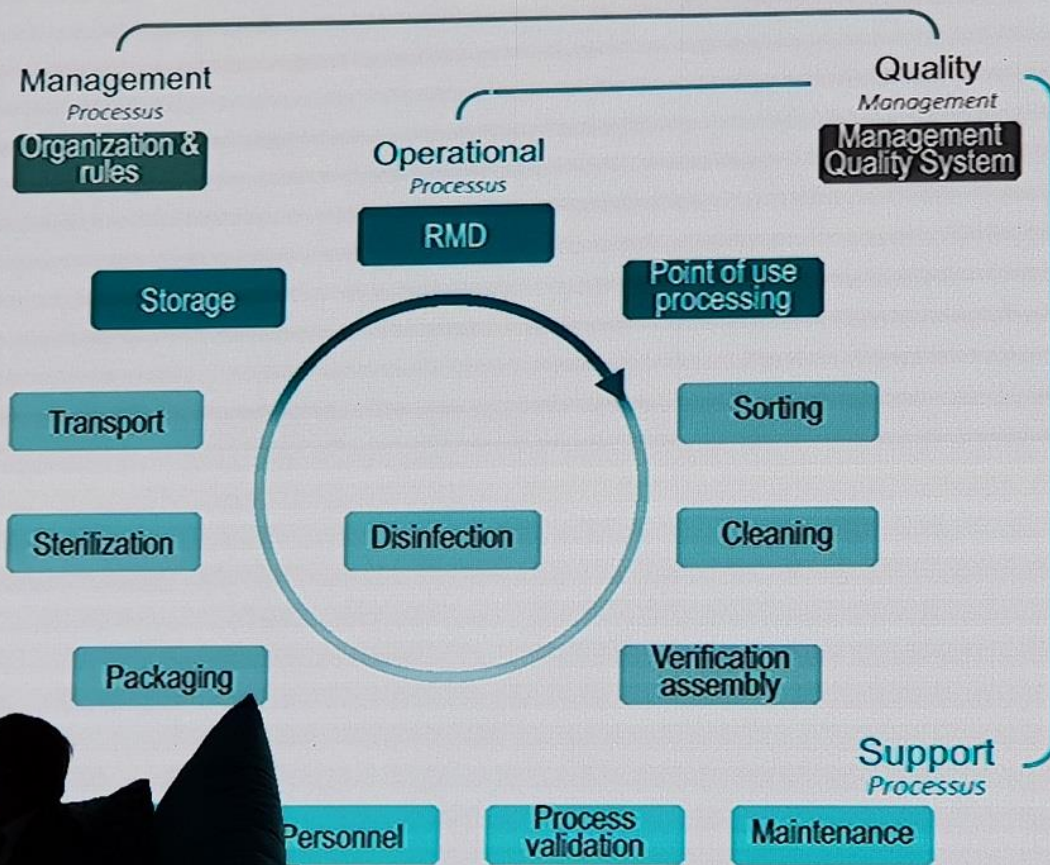


## Structure

- Map to be defined
- Vocabulary to be agreed
- Chapters (prion, purchase...)
- Graphic to be improved

Worldwide harmonized practices, an inaccessible challenge ?



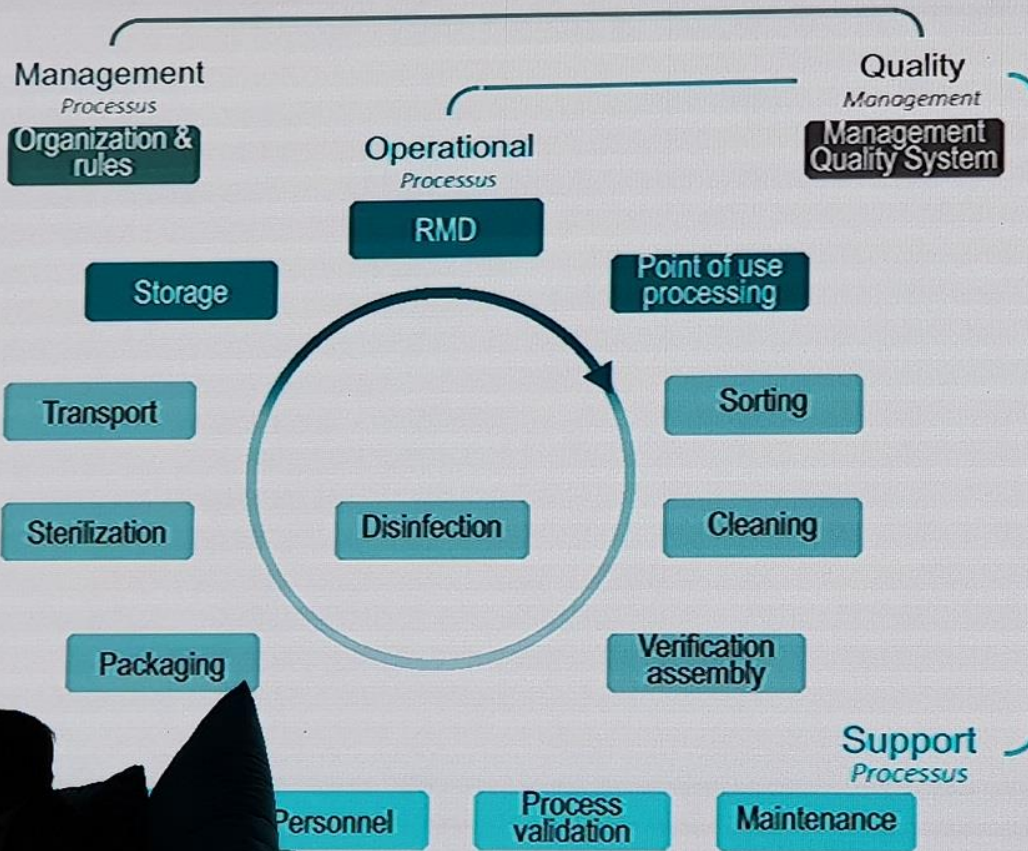


Interactivity, flexibility

Links

Independent chapters – ease up

Worldwide harmonized practices, an inaccessible challenge ?



# Flexibility

## Process validation



### Principles

- Cleaning
  - Manual cleaning
  - Washer-disinfectors
  - Ultrasonic cleaners
- Packaging
- Sterilization



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# CONCLUSION

- WFHSS promotes international Guidelines as harmonized practices to improve the global level
- Can be a source of Inspiration for national guidelines
- Basics for education courses and certification
- Basics of a win/win collaboration with industry
- First chapters available January 2019