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Analysing hazards : a tool for quality management


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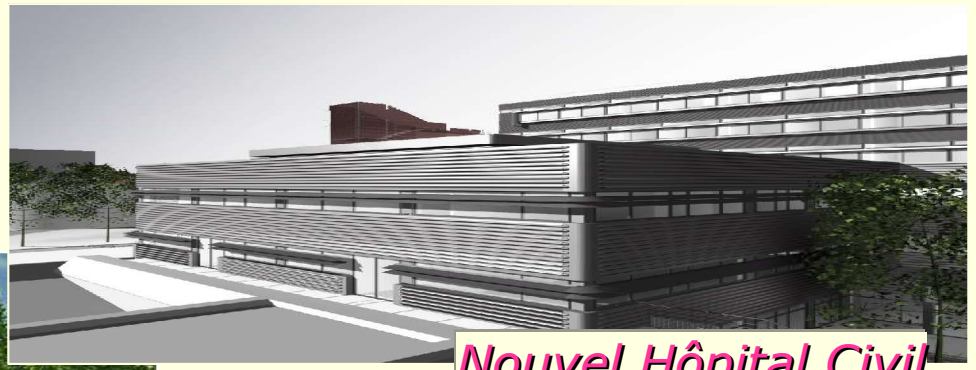
Sterilization activity

- University Hospital of Strasbourg
  - 2600 beds
  - 45 theatres
  - 70 dental seats



Nouvel Hôpital Civil

Hôpital de Hautepierre

- Sterilization activity
  - 60 operators
  - 3 supervisors
  - responsability : pharmacist (~ consultant)

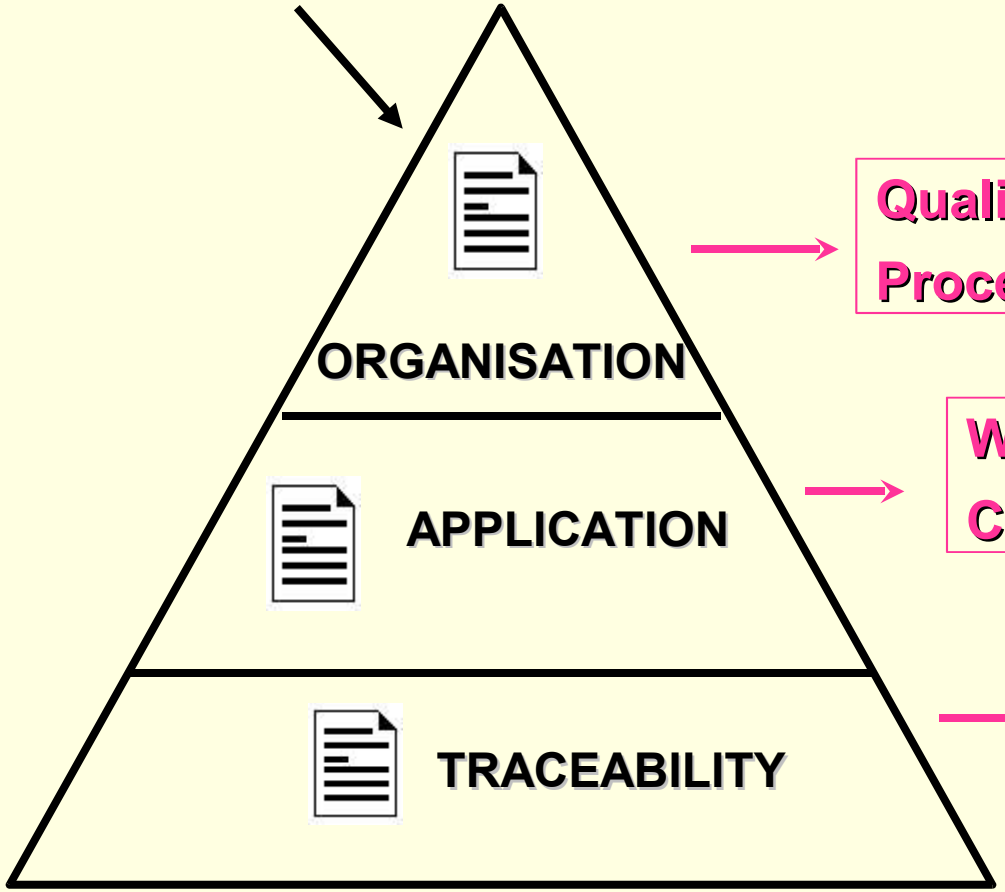
Since 1995

- development of quality management
  - quality policy
  - sterilization education and training
  - quality education
  - definition of person in charge of quality management
- building of a specific quality system for sterilization activity

NF EN ISO 9000, 9001

Quality system

National regulation / Standard / Bibliography / Guidelines …



Quality manual
Procedures documents

Work instructions
Check lists

Quality records
Control and treatment of non confirming products

2000 : a new department

- a modern architecture for our CSSD
  - new areas
  - new organisation
- difficulty for the operators to be enough involved in quality assurance
- development of analysing hazards adapted to sterilization process

→ H.A.C.C.P.

Hazard Analysis Critical Control Point

H.A.C.C.P. method

H. A.

Hazard Analysis

the process of collecting and evaluating information on hazards associated with sterilization process under consideration to decide which are significant

C. C. P.

Critical Control Point

a step at which control can be applied and is essential to prevent or eliminate a sterilization hazard or reduce it to an acceptable value

Definitions

- hazard
  - an event that may impair, in absence of its control, quality of medical devices or sterilization process and induce a negative effect for health.
- critical point
  - any step at which biological, chemical or physical factors can be controlled

objective of sterilization process

✪ microbiological and functional safety for medical devices

✪ with an effective logistic

Developping a HACCP plan

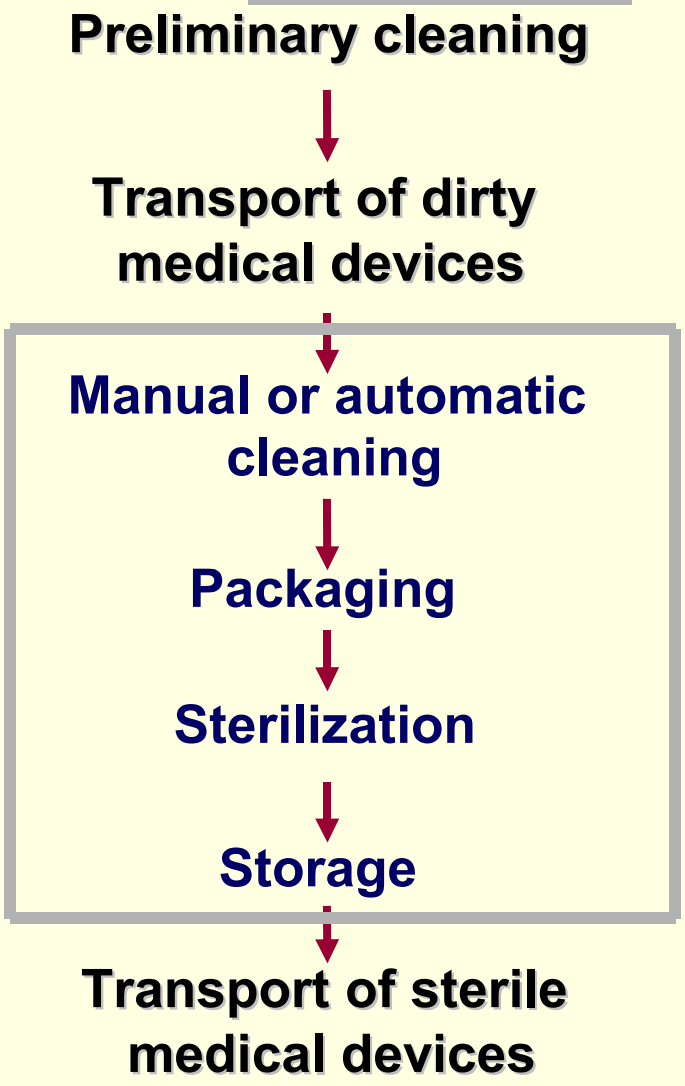
1. → conduct a hazard analysis
2. → determine critical control points
3. → establish critical limits for each point
4. → establish monitoring procedures
5. → establish corrective actions
6. → establish verification procedures
7. → establish record-keeping and documentation procedures

Preliminary tasks

- determine HACCP team : a work group with all professionnals of sterilization
- conduct a specific training
- describe the aim of the study
  - steam sterilization (134°C, 18 min)
  - identification of microbiological and functional hazards
- describe the sterilization process

Conduct a hazard analysis

- develop a flow diagram which describes the process
- for each stage
- type of hazard
  - microbiological
  - functional
- method
  - brain storming session
  - collection of non confirming products and complaints of customers
  - Ishikawa method



microbiological hazards for cleaning

Potential hazard	Cause 1	Cause 2	Cause 3	Preventive measures
S	Loading of basket which decreases cleaning efficacy	Many instruments in each basket Medical device with lumen	Bad knowledge of medical devices	Training Cleaning procedure Data records of each medical devices
M	Medical devices which are waiting a long time before cleaning	No cleaning during the night		Pre-cleaning of medical devices with a mecanical action Specific tray
R	Water during packaging	Bad drying	Problem with washer disinfector	Verification of each medical device before packaging Training Cleaning procedure

S = survey, M= multiplication, R = recontamination (MD=medical device)

functional hazards for cleaning or transportation

Potential hazard	Cause 1	Cause 2	Cause 3	Preventive measures
D **F**	Corrosion of medical devices	Quality of water in washer disinfector	No specifications	Chemical quality of final rinse water Periodic control of water
L **B** **D** **F**	Loading of the baskets during transportation	Bad training No sufficient time No adapted trolley		Education and training Organisation New trolleys

L = loss , B = breakage , D= damaged medical device, F = damaged function

Identification of CCP

- CCP decision tree
  - a sequence of questions to assist in determining whether a control point is a CCP
  - example : sealing during packaging stage

Q 1 = Is there a specific hazard at this step ?

YES NO → NOT A CCP

Q 2 = Does specific measure exist at this step to prevent this hazard ?

YES NO → Modify step, process or product

Q 3 = Is this step efficient to eliminate or reduce the likely occurrence of this hazard to an acceptable value ?

NO **YES**

Q 4 = Could this hazard increase to an unacceptable level ?

YES NO → NOT A CCP

Q 5 = Will a subsequent step eliminate hazard or reduce its likely occurence to an acceptable level ?

YES **NO** → **It's a CCP**

Identification of critical points

- Critical Control Points
  - transport
  - sealing
  - loading medical devices before sterilization
  - sterilization
  - …

→ specific monitoring for each CCP

  - 2 types
    - **automatic**
    - **manual**

For each Critical Control Points

- Establish
  - critical limit of each CCP
  - frequency of control
  - responsabilities
  - control records

Examples

CCP	Critical limits	Monitoring	Records	Responsability
Sterilization phase during cycle	Temperature 134°C [-0°C ; +3°C]	Each cycle	Diagram with temperature and pressure	Operator
Integrity of sealing	0	After each packaging Monthly	Packaging traceability Specific HACCP document	Operator Superviser

H.A.C.C.P **STERILIZATION DEPARTMENT**

VERIFICATION
CCP : SEALING

Date :

Name : Function :

1- Temperature of sealing = 180°C ❒ yes ❒ no

Sample of 10 sealed pouches :

2- Number of pouches with no secure seal :
3- Number of pouches with no linear seal :
4- Number of pouches with bad seal (crease) :

Notes :

Control of critical point : ❒ yes ❒ no

Corrective actions

Delay to be effective :
Responsabilities :

Pharmacist : **Direct superviser :**

Assessment of this study

- methodical analysis
- increase of prevention system
- development of monitoring
  - specific document (HACCP verification schedule)
  - traceability of each control
  - identification of non conform products

Positive points

- collective involvment of the staff
  - increase relation with our customers
    - **theatre**
    - **maintenance staff**
    - **...**
  - increase dynamic quality system

Specific attention

- grade hazards and their specific preventive measures
  - **criticity index** =
    severity x detectability x frequency
- a long time to develop this study
- importance of communication with the team

Improvment of quality management

- **level 1**
  - no quality system
    - education and training of operators, quality policy, quality manual, procedures documents
- **level 2**
  - operational quality system
    - analysis of repetitive problems, development of corrective actions
- **level 3**
  - operational quality system, corrective actions
    - hazard analysis and critical control points
    - development of preventive actions
- **level 4**
  - efficient quality system with preventive actions
    - development of valuation
    - internal quality audit


BIGGER, BETTER, TOGETHER
HOMECHOICE
Go-Ahead
Camberwell
Westminster
Piccadilly Circus
Oxford St
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