Analysing hazards : a tool for quality management

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Sterilization activity

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

- Sterilization activity
  - 60 operators
  - 3 supervisors
  - Responsibility: 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 …
- ORGANISATION
- APPLICATION
- TRACEABILITY
- 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
Developing 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**

<table>
<thead>
<tr>
<th>Potential hazard</th>
<th>Cause 1</th>
<th>Cause 2</th>
<th>Cause 3</th>
<th>Preventive measures</th>
</tr>
</thead>
</table>
| **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**

<table>
<thead>
<tr>
<th>Potential hazard</th>
<th>Cause 1</th>
<th>Cause 2</th>
<th>Cause 3</th>
<th>Preventive measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>L</td>
<td>Loss</td>
<td>Loss</td>
<td>Prevention measures</td>
<td>Chemical quality of final rinse water</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Periodic control of water</td>
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<tr>
<td>B</td>
<td>Breakage</td>
<td>Breakage</td>
<td>Prevention measures</td>
<td>Education and training</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Organisation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Damaged medical device</td>
<td>Quality of water in washer disinfector</td>
<td>Prevention measures</td>
<td>New trolleys</td>
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<tr>
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<tr>
<td>D</td>
<td>Damaged medical device</td>
<td>Quality of water in washer disinfector</td>
<td>Prevention measures</td>
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<tr>
<td>F</td>
<td>Damaged function</td>
<td>Quality of water in washer disinfector</td>
<td>Prevention measures</td>
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</tbody>
</table>

**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 occurrence 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
  - responsibilities
  - control records
### Examples

<table>
<thead>
<tr>
<th>CCP</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Records</th>
<th>Responsability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization phase during cycle</td>
<td>Temperature 134°C [-0°C ; +3°C]</td>
<td>Each cycle</td>
<td>Diagram with temperature and pressure</td>
<td>Operator</td>
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<tr>
<td>Integrity of sealing</td>
<td>0</td>
<td>After each packaging</td>
<td>Packaging traceability</td>
<td>Operator</td>
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<td></td>
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<td>Monthly</td>
<td>Specific HACCP document</td>
<td>Supervisor</td>
</tr>
</tbody>
</table>
H.A.C.C.P

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 supervisor :
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 involvement 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
Improvement 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