

# AIOS

**ASSOCIAZIONE ITALIANA OPERATORI  
SANITARI** ADDETTI ALLA STERILIZZAZIONE  
(Italian Association of Sterilization Operators working  
in health care facilities)

Flavia Bossi  
Presidente AIOS

Maggio 2007



# WFHSS 2007 - WORLD CONFERENCE FOR HOSPITAL STERILE SUPPLY

Baden - Austria

## The health care professionals' role in the sterile Medical Devices' manufacturing process

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# Mission

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- Main importance of the patient, final user of all the activities of the service.
- Continuous research and innovation.
- Guarantee of safety through the whole sterilization process.
- Benchmarking, carried out as constant comparison with other sterilization services operating in the same field, in order to improve performances and make them competitive.



# Annual planning

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- **Quality targets**

- **Productivity targets**

1. Reduction of risks correlated to the process.
2. Assessment of the near miss.
3. Management of practical resources of the central sterilization service.
4. Management of financial resources.
5. Management of human resources.
6. Planning of training courses for the central sterilization service personnel.
7. Planning of meetings for the spread of information regarding the quality certification to all the central sterilization service personnel.

# Operational planning

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- Activity plans
- Procedures
- Instructions
- Rules

1. Daily activity plans.
2. Weekly activity plans.
3. General operational procedures.
4. Washing, packaging and sterilization procedures.
5. Operating instructions (in details).
6. Software management procedures.

# A good recipe



technology

competence

professionalism



**Who????!!!**

# Anyone???

## Then, if he is not able to face any situation?

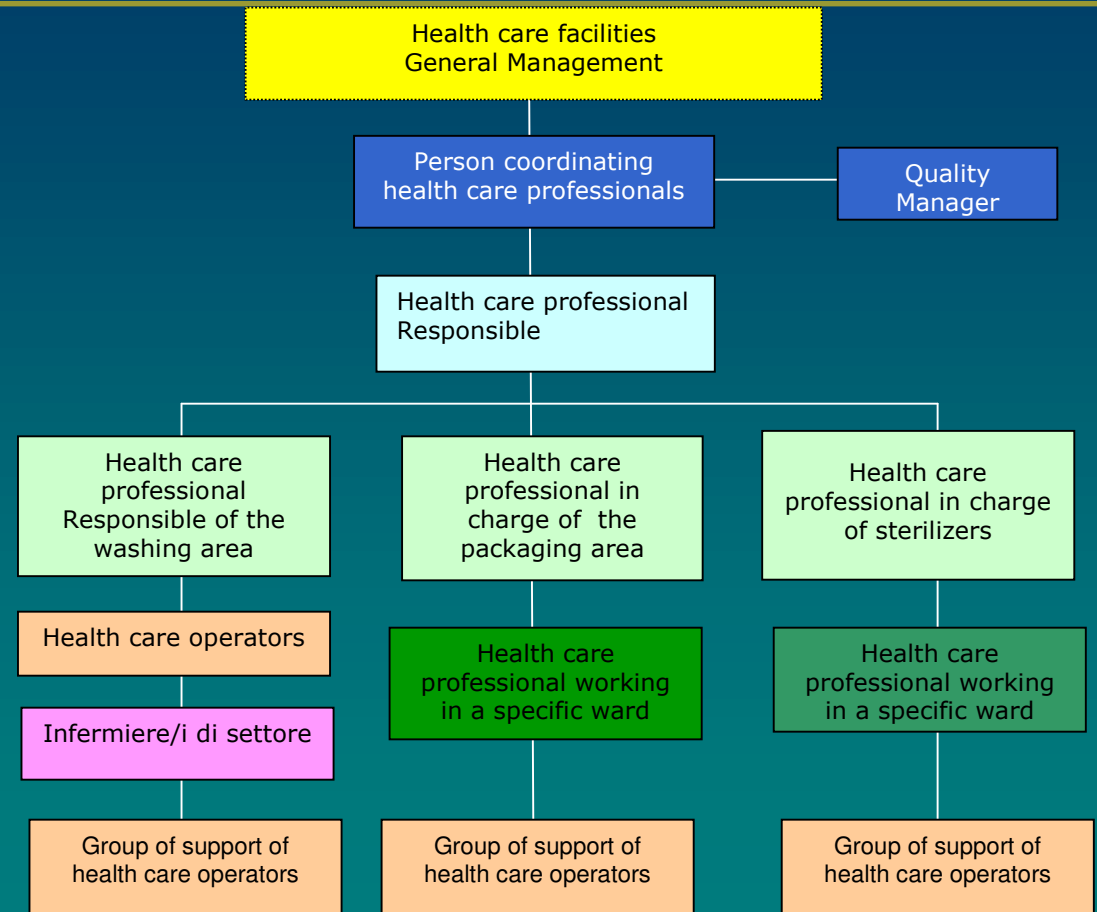
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- film

# The health care professionals organization

Why an health care professional?

- Prevention of hospital infections





# As damages may sometimes occur...

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■ film

**health care operators in charge of surgical instruments**

**specific knowledge  
of operating  
procedures time**

**specific knowledge of  
surgical instruments**

**Management of surgical instruments and  
implantable devices**

# Packaging process

## Health care operators competence

- Receiving devices
- Devices identification
- Risks analysis
- Drawing up of operating Directions for Use
- Drawing up of check lists
- Devices traceability
- Validation
- List describing controls
- Monitoring steps
- Acceptance of the final product



# Acceptance of new devices

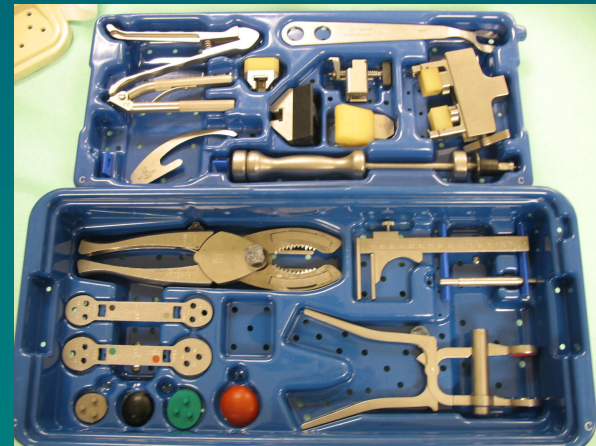
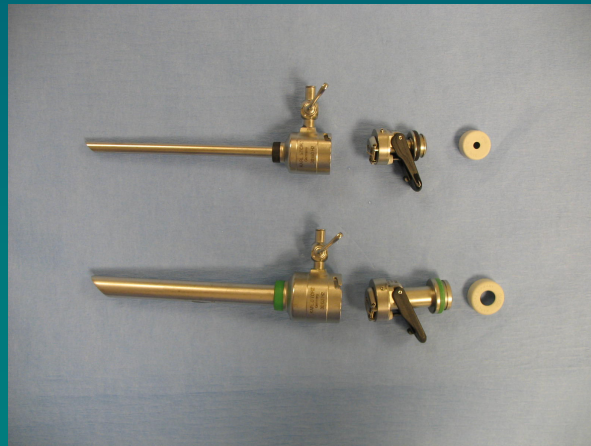
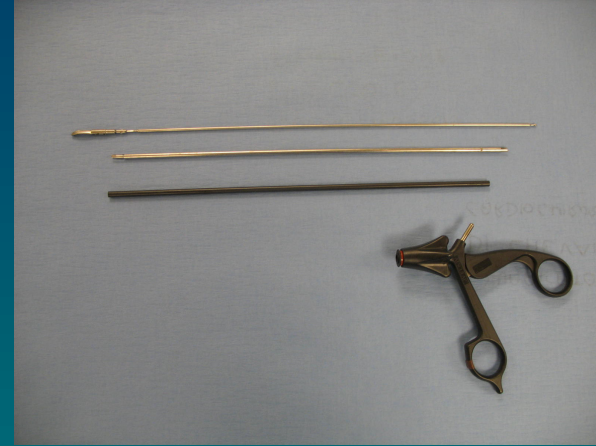
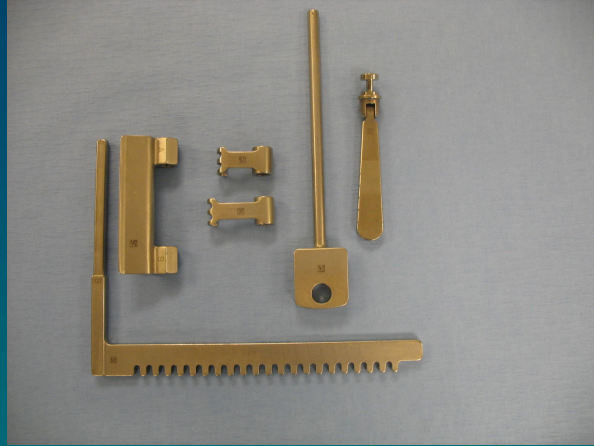
## Suggestions on the documents to check and collect

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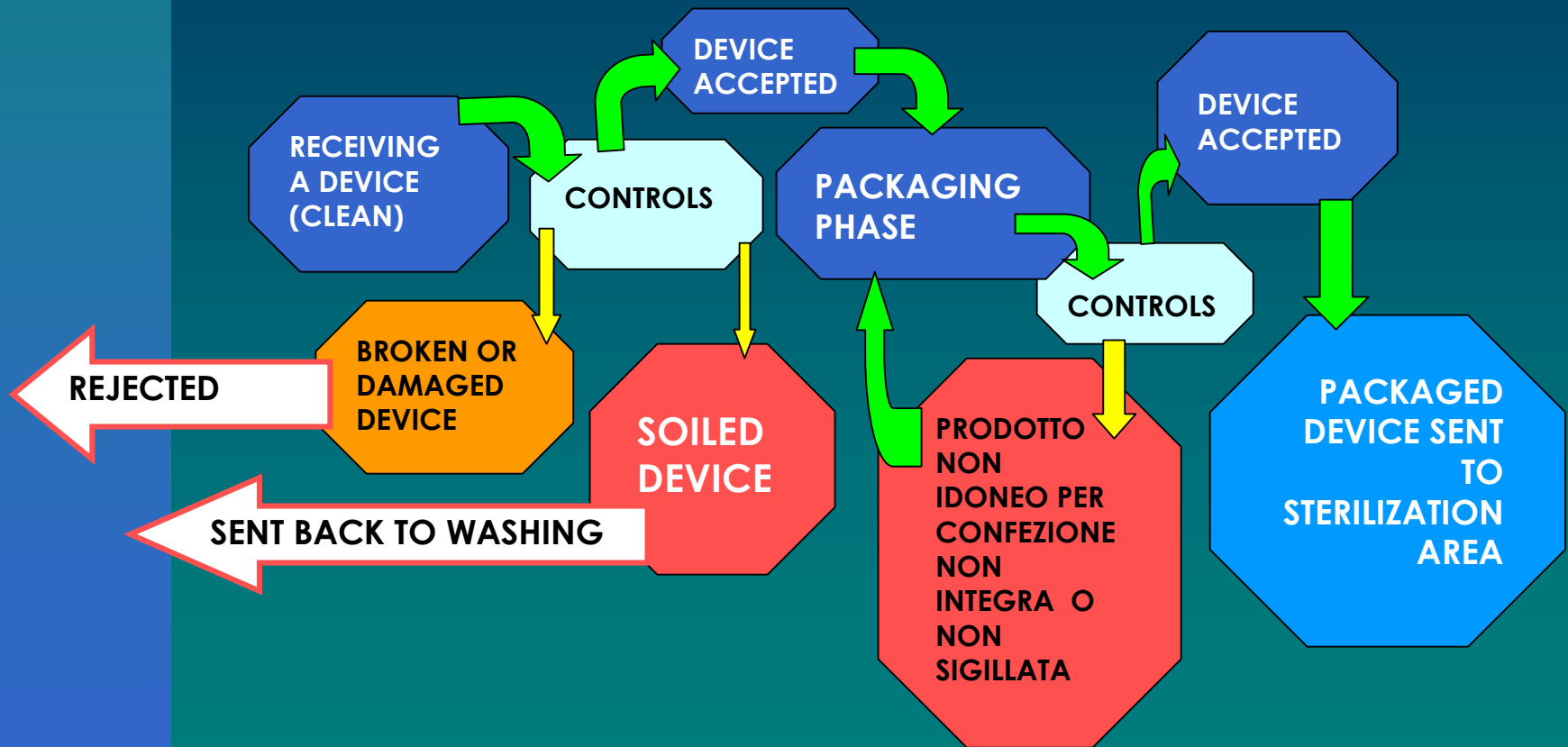
- Check the compliance with the EC Directive
- Collect the technical data sheets
- Take a picture of the device
- Recording the device position (on inventory, in a specific procedural kit, etc.)
- Ascribing the device to the end user
- Defining the packaging system
- Risks analysis



# Examples of the picture recording of different medical devices



# Packaging area controls



# Packaging for terminally sterilized medical devices

## Standard of reference

EN ISO 11607



~~EN UNI 868-1~~

since April 2007

The **EN 868-2/10** series specify particular requirements for a range of commonly used materials and are still in force

in 2 Parts:  
**ISO 11607 Part 1**  
Requirements for materials, sterile barrier system and packaging systems

**ISO 11607 Part 2**  
**Validation requirements for forming, sealing and assembly processes**

# Terms and definitions

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- **3.22 Sterile barrier system (SBS)**

Minimum package that prevents ingress of microorganisms and allow aseptic presentation of the product at point of use.

- **3.13 Protective packaging (PP)**

Configuration of materials designed to prevent damage to the sterile barrier system and its content from the time of their assembly until the point of use.

- **3.10 Packaging system**

Combination of the sterile barrier system (SBS) and protective packaging (PP)

- **3.11 Performed sterile barrier system**

SBS that is supplied partially assembled for filling and final closure or sealing

Example: pouches, bags and open reusable containers.



# Packaging validation

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The process for obtaining, recording and interpreting the required results, establishing that a process will allow to have a product constantly complying with the requirements.

A controlled and documented **process** carried out always with the same method: process repeatability and reproducibility.

# Installation qualification



Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

The aspects to consider are:

- Are the operators trained to the use of the equipment?
- Who has been authorized to the use of the equipment?
- Has the training been documented?
- Does the equipment meet the manufacturing demands?
- Are the controls to carry out for obtaining high quality standards specified?

# Operational qualification

This process is intended to give evidence that the installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Elements that have to be taken into consideration:

- Is the sealing temperature correct?
- Are there some controls allowing to check if the packaging systems have been sealed at too low or too high temperature?
- Are the sealing speed and pressure suitable for that type of material?
- Is there an alarm signal, a warning system for advising if the predetermined limits have not been reached or have been exceeded?
- Are those critical process parameters listed in the operating manual provided by the manufacturer?



# Performance qualification

Process of obtaining and documenting evidence that:

- Equipment has been provided and installed in accordance with its specifications.
- Sterile Barrier Systems are realized in accordance with predetermined criteria, in order to “manufacture” and “distribute” products meeting the required specifications.

**It is the sum of the two previously mentioned qualifications**



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Presidente AIOS

# Packaging validation: critical process parameters

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## ■ Reusable containers



- Assembly of the set according to validated instructions.
- Replacement of the filter in disposable systems.
- Verifying the number of sterilization cycles run with a permanent filter.
- Visual inspection of the integrity of the gasket.
- Visual inspection of the integrity of the sterilizer.
- The effective cleaning.

## A close-up photograph of the bottom of a green medical waste container. A metal handle is attached to the bottom, and a label on the handle reads "OSP. SAN GERARDO 295". The container is placed on a light blue surface.

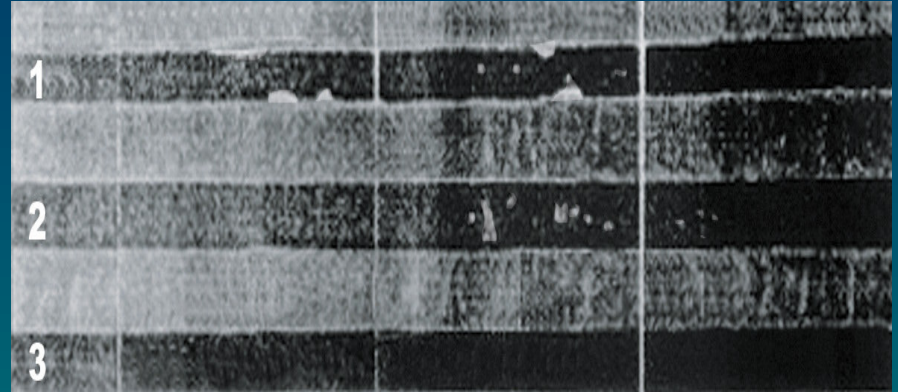
**AIOS**  
ASSOCIAZIONE ITALIANA  
OPERATORI SANITARI  
ADDETTI ALLA STERILIZZAZIONE



# Difficulties related to wrapped packs and pouches/bags sealing

## ■ **Wrapped packs:**

- Human “contribution”
- Operator training.
- Working out specific operating instructions in compliance with DIN 58953.



## ■ **Sealing of pouches:**

- Procedure related to the control of sealing parameters.
- Routine monitoring of sealers.
- Schedule of tests to be performed.

# Protective Packaging

- Already mentioned in the EN 868 standards.
- Its function is to prevent damage to the sterile barrier system during storage and transport.
- In hospitals this protective packaging is put on the pack after the sterilization cycle using a thermo-drawing film or something else.





# Traceability

- Immediate traceability.
- Legal traceability.
- Managerial traceability.
- Minimize mistakes in central sterilization services
- Increasing of quality.
- Increasing of patient safety.
- Use of means as added value.

onfezionamento Kit

Specialistica: ORTOPEDIA IN CONTO VISION

Kit: BIOIMPIANTI CHIODO GAMMA STRUM. 2

Viraggio: \_\_\_\_\_ Stato: \_\_\_\_\_

Data: 16/04/2007 Blocco: Blocco C

Quantità: 1 Urgenza: \_\_\_\_\_ Ubicazione: Centrale Sterilizzazione

Sterilizzare: Vapore 134 - 30 gg Vapore 134 30

Cestello: SCATOLA BEIGE Numero: \_\_\_\_\_

Totale str.: 33/23 Distribuz.: Lista Visione: ☐

Note: scheda di ricondizionamento per PSG CSG MO. 008

Data Matrix: \_\_\_\_\_ Operatore: SALZANO CINZIA

QtyPrev	#	Qty	Descrizione	Codice	Note	Variaz	Image
1	#	1	INSERITORE /ESTRATTORE CON MASSA BATTENTE PIU' RONDELLA	140030655			
1	#	1	MANDRINO DI JACOBS	140030555			
1	#	1	CHIAVE	S.C.			
2	#	2	CILINDRI	140030545			
1	#	1	PUNTERUOLO MANICO A "T"	140030605			
1	#	1	CHIAVE CARDANICA	140030600			
2	#	2	BUSSOLOTTI	140030630			
1	#	1	INSERITORE MANICO A "T" NERO	140030550			
1	#	1	MANDRINO PIU' ROTELLA NERA	S.C.			
1	#	1	ESTRATTORE CANNI 6/10	140030675			

Variazioni

# Thanks for your kind attention

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■ film