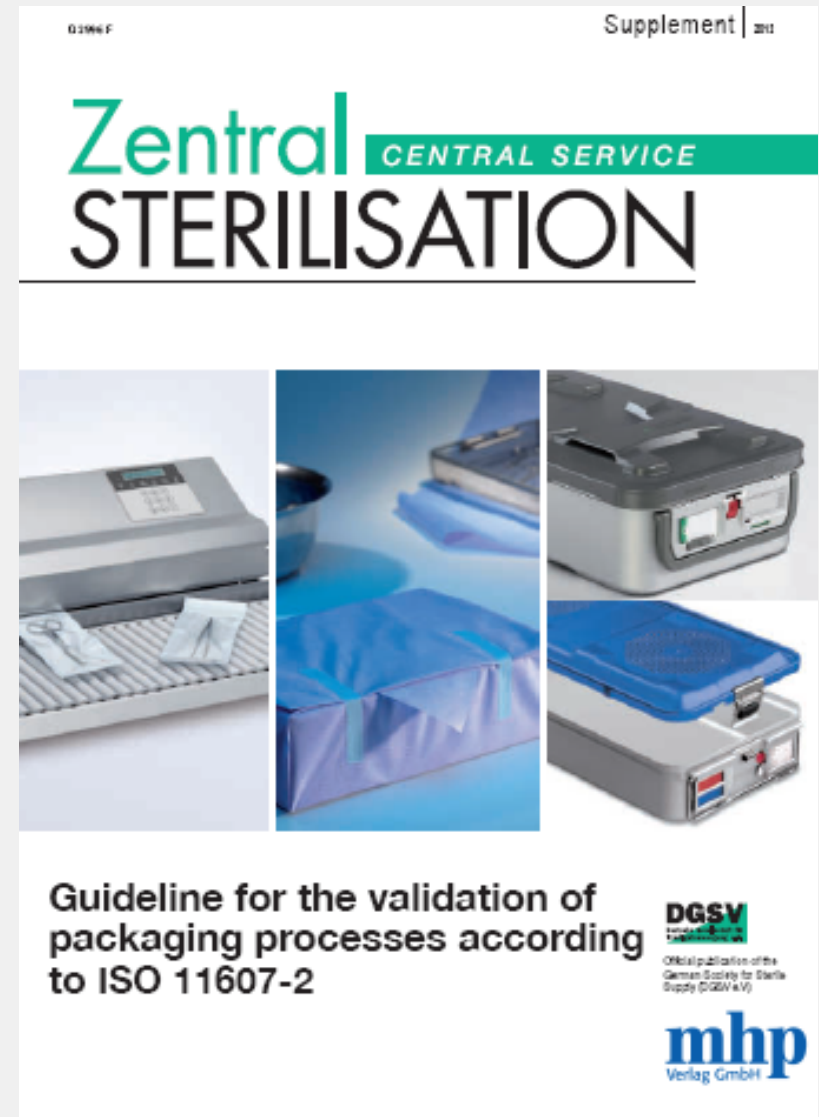


Guideline for the validation of packaging processes according to DIN EN ISO 11607-2



A guideline for the validation of
packaging processes?

Why ???

What have been the motives for
developing this guideline?

The work group's motives for developing the guideline



It has been worked on the guideline for this process already in detail within the 1st revision of the guideline in 2008

The work group's motives for developing the guideline

✓ A guideline for pouch, reel or bag sealing exists already

- Well – what about the **other** packaging processes?
- Don't they play a **role** within **the whole process**?
- How do those packaging processes **fit into the validation of sterilization processes**?

The work group's motives for developing the guideline

What is the focus for bought-in packages:

- Quality?
- Price?
- Who decides which packages, which quality will be bought?
- Do these products accord to normative requirements?
- Do validated processes play a role?

The work group's motives for developing the guideline

- Dissatisfaction of people working with topics as cleaning, disinfection and sterilization of medical devices as well as users, e.g.:
 - Gluing of packages
 - Materials which are difficult to handle
 - Poor quality of adhesive tape
 - ...

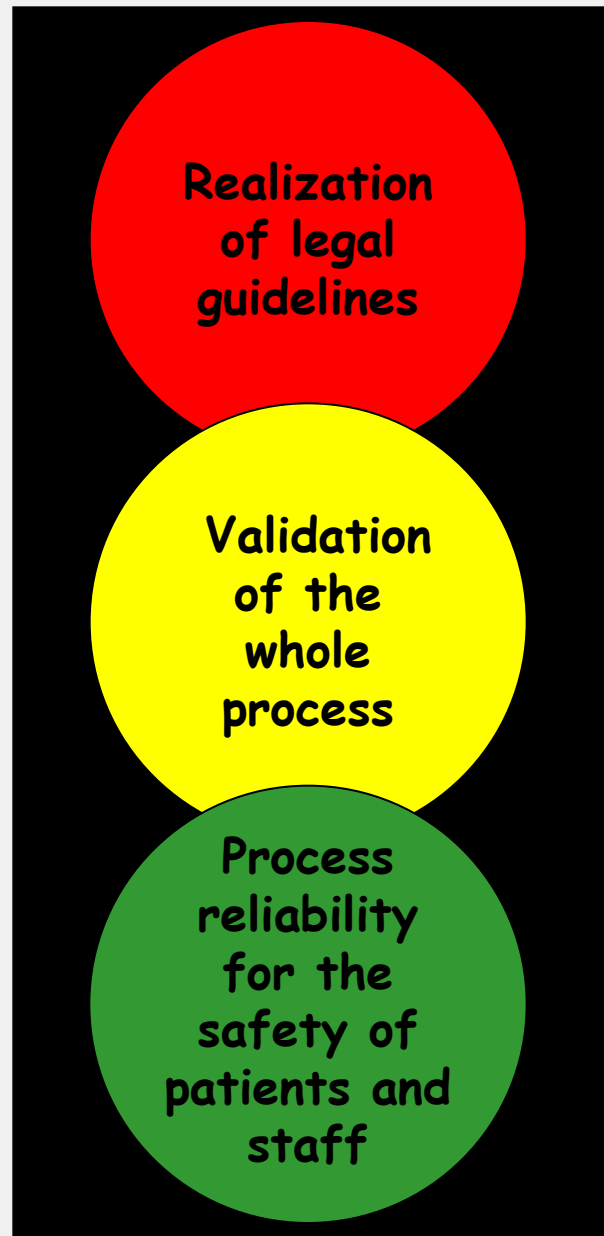
The work group's perspective:

The guideline for the pouch, reel and bag sealing is the beginning in the validation of packaging processes.

We asked ourselves, does it make any sense to continue with our work?

What was our purpose continuing with this work?

**The workgroup's
purpose**



Validated processes?

Yes - automated cleaning and disinfection processes

Yes - heat sealing processes

Yes - sterilization processes

automated processes

... and the manual processes?

- **Manual cleaning and disinfection processes**
- **Visual inspections**
- **Maintenance process**
- **Operational qualification**
- **Packaging of medical devices**
 - **Sample standard operating procedure heat sealing**
 - **Sterilization sheet's folding and wrapping**
 - **Filling and closing of reusable sterilization containers**
- **Approval**
- **Storage and transport**



... and the manual processes?

- ✓ **Manual cleaning and disinfection processes**

 - Visual inspection**

 - Maintenance process**

 - Operational qualification**

- ✓ **Packaging of medical devices in pouches, reels and bags**

- ✓ **Soft packaging (Sterilization sheet's folding and wrapping)**

- ✓ **Container packaging (reusable container)**

 - Approval**

- ➔ **Storage and transport**

Quality Management System

```
graph TD; A[Quality Management System] --> B[Basis for a validation or rather always comprehensible and reproducible processes]; B --> C[Without a Quality Management System a validation is not possible. All steps have to be defined and documented.];
```

Basis for a validation or rather always comprehensible and reproducible processes

**Without a Quality Management System
a validation is not possible. All steps have to be defined and documented.**

Normative bases for writing this guideline:

DIN EN ISO 11607-1 (2009)	Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11607-2 (2006)	Validation requirements
DIN 58953, Part 1 (2010)	Terms and definitions
DIN 58953, Part 7 (2010)	Application technique of sterilization sheets, heat sealable transparent bags and tubing
DIN 58953, Part 8 (2010)	Logistics of sterilized medical devices
DIN 58953, Part 9 (2010)	Application technique of containers

When using sterilized medical devices the packaging is part of the sterilization process and therefore the packaging is to validate as well.

The packaging process

Pouch, reel or bag sealing



Sterilization sheet's folding and wrapping



Filling and closing of reusable containers



**Validation using the example
of the following packaging
process:**

**Folding and wrapping of
sterilization sheets**



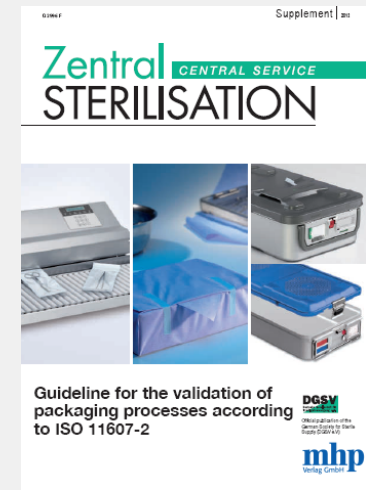
Initial validation

Initial operating



Agenda

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation



The practical cycle with the help of the guideline

→ Requirements

→ Drafting of a validation plan

→ Conduct of validation

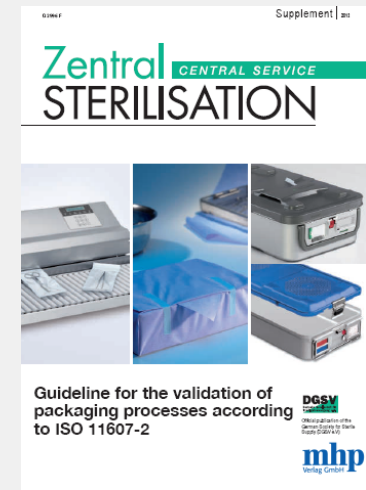
→ Drafting of a validation report

→ Formal approval of the validation process

→ Process control and monitoring

→ Process changes and revalidation

→ Table of the process validation



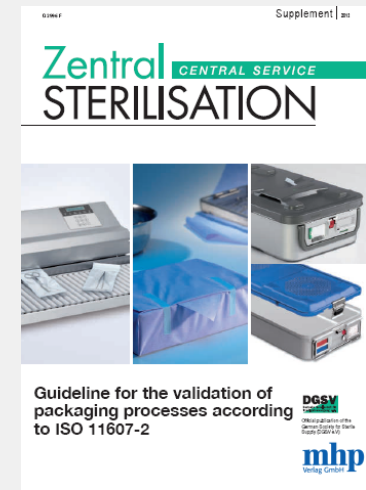
Requirements

Request supporting documents by the manufacturer:

- CE confirmation of conformity = **European minimum requirement for quality and product safety**
- ISO 11607 / EN 868
- Product specification and/or technical data sheet
- ISO 9001 certificate

The practical cycle with the help of the guideline

- Requirements
- **Drafting of a validation plan**
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation



Drafting of a validation plan

Content:

- Competences
- Description of the packaging process
- Description of the materials/equipment
- Description of another indicator used
- Description of sterilization process
- Qualification steps (IQ, OQ, PQ)
- Formal approval of validation/revalidation by the operator

Validation plan checklist „sterilization sheets´ folding and wrapping“

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Annex B.1 Validation plan checklist (sterilization sheets´ folding and wrapping)

Initial validation
 Recalibration (at regular intervals, only after major repair/ failure)
 Recalibration of essential reasons (e.g. new sterility)

I.6) Competence

Name of individual operator	
Location	
Full name (name of persons, or companies, conducting validation)	
Business for business/individual business	

I.7) Description of reusable container

Manufacturer name	
Designation name	
Size (lit)	
Can air vent	
Manufacturer's CE certified sterilization analysis (211)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
ISO 11887 Part 1 conformity (211)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
Manufacturer's CE certificate analysis (211)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
Clear (type of packaging material) (see note 10)(1)	<input type="checkbox"/> Clear paper <input type="checkbox"/> Polystyrene <input type="checkbox"/> PET or other suitable
Manufacturer's specific size and finish sheet analysis(2)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
with information on:	
Bar strength (3) (total weight) (4)	<input type="checkbox"/>
Gas permeability with respective certification process(5)	<input type="checkbox"/> ISO 684 <input type="checkbox"/> ISO 15868 (part 2) <input type="checkbox"/> FCI (FCMI (sterilizable))
	<input type="checkbox"/> ISO 684 <input type="checkbox"/> Other
Label on protective and inner packaging (EN 60920006)(6)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence

44 The CE mark must be affixed to the outer packaging. The CE mark must not lead to confusion applied by the manufacturer or performance of the system.
 45 Conformance with ISO 11887 Part 1 at validation process based in general (see also for details EN 60920006). CE conformity assessment with ISO 11887 Part 1 was done only during development.
 46 See Annex Example for sheet strength test methods.

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Equipment number(1)	<input type="checkbox"/>
	<input type="checkbox"/>
Manufacturer's name(2) and	<input type="checkbox"/>
	<input type="checkbox"/>
Manufacturer's CE certificate analysis(3)	<input type="checkbox"/>
ISO 11887 Part 1	<input type="checkbox"/>
analysis(4)	<input type="checkbox"/>

1 If not, the assessment will be done in accordance with the manufacturer's instructions.

211 (see note 10)(1)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

211 must include no air to be led out as the valid when process ends used.

Closing system with on/off indicator

operator	<input type="checkbox"/> Inductive tape to closed lid cover (system of additional)(1)	<input type="checkbox"/> Inductive tape with indicator (2)(1)
CE certificate analysis(2)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
ISO 11887 Part 1	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
analysis(3)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence
	<input type="checkbox"/> ISO 684 <input type="checkbox"/> ISO 15868 (part 2) <input type="checkbox"/> FCI (FCMI (sterilizable))	<input type="checkbox"/> ISO 684 <input type="checkbox"/> Other
with information on:		
Bar strength (3) (total weight) (4)	<input type="checkbox"/>	<input type="checkbox"/>
Gas permeability with respective certification process(5)	<input type="checkbox"/> ISO 684 <input type="checkbox"/> ISO 15868 (part 2) <input type="checkbox"/> FCI (FCMI (sterilizable))	<input type="checkbox"/> ISO 684 <input type="checkbox"/> Other
	<input type="checkbox"/> ISO 684 <input type="checkbox"/> Other	<input type="checkbox"/>
Label on protective and inner packaging (EN 60920006)(6)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Evidence

44 The CE mark must be affixed to the outer packaging. The CE mark must not lead to confusion applied by the manufacturer or performance of the system.
 45 Conformance with ISO 11887 Part 1 at validation process based in general (see also for details EN 60920006). CE conformity assessment with ISO 11887 Part 1 was done only during development.
 46 See Annex Example for sheet strength test methods.

47 Evidence can be provided either by a closed lid cover or an on/off indicator.
 48 The on/off indicator system is considered as a separate qualified material system (EN 60920006).

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<input type="checkbox"/> ISO 684 (part 2)	<input type="checkbox"/>	
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

FCMI (sterilizable)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

ISO 15868 (part 2)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

ISO 684

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

ISO 15868 (part 2)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

Corrosion & Suppl 2012 ANNEX B.11 29

ISO 684 (part 2)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

FCMI (sterilizable)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

ISO 15868 (part 2)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Where?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Evidence

ANNEX B.11 29

Results not OK (2), CE mark FCI not issued (3) or at least in each module in performance report (3) (see 10) as far as possible to use in some steps.

Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>
Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>
Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>
Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>
Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>
Completed	<input type="checkbox"/>
Unauthorized/uncontrolled during validation on	<input type="checkbox"/>

Invalidated by the operator

Initial

Name _____

Signature _____

Annex B.1 Validation plan check list (to be filled in before the FOLDING and MAPPING)

- Initial validation
 Revalidation (at regular intervals, only parts relevant repeat tested)
 Revalidation of special reasons (e.g. reformulation)

I a) Competence

Name of tested (as supervisor)	
Location	
Holder (name of persons, or companies, conducting validation)	
Responsible for overall validation (as responsible)	

I b) Description of usable container

Manufacturer			
Designation			
Supplier			
Container person			
Manufacturer's CE certificate publication available? ¹⁾	<input type="checkbox"/> Yes	CE No	<input type="checkbox"/> Evidence
ISO 13485 Part 1 certificate only? ²⁾	<input type="checkbox"/> Yes	CE No	<input type="checkbox"/> Evidence
Manufacturer's QM certificate available? ³⁾	<input type="checkbox"/> Yes	CE No	<input type="checkbox"/> Evidence
Description of packaging material (specify material) ⁴⁾	<input type="checkbox"/> Clear paper	CE No/series	<input type="checkbox"/> CE E mark systems
	<input type="checkbox"/> Tinplate material	CE No:	
Manufacturer's specific data and technical sheet available ⁵⁾	<input type="checkbox"/> Yes	CE No	<input type="checkbox"/> Evidence
with information on			
Net/bruto weight / total weight (g/ml) ⁶⁾	<input type="checkbox"/>		
Compatibility with respective sterilisation process ⁷⁾	<input type="checkbox"/> ETO/ETA	<input type="checkbox"/> EO (ethylene oxide)	<input type="checkbox"/> FGD/FA (formaldehyde)
	<input type="checkbox"/> H ₂ O ₂ (peracetic)	CE No:	
Label as protective and inner packaging (ISO 15823:2006) ⁸⁾	<input type="checkbox"/> Yes	CE No	<input type="checkbox"/> Evidence

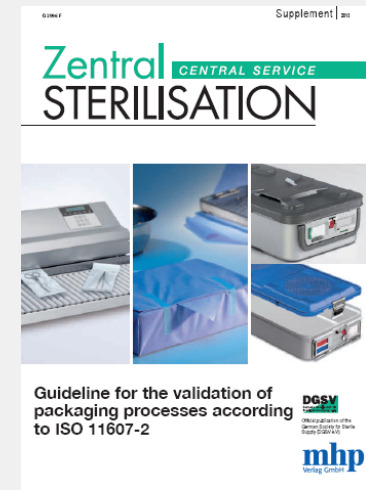
¹⁾ The CE mark must be affixed to the outer packaging. The CE mark must not be fixed to the containers supplied by the manufacturer or (pre)filled material manufacturer.

²⁾ Certificate only with ISO 13485:01 certificate publication in general (includes certificate only with ISO 13485:01, CE certificate only certificate only with ISO 13485 Part 1 are checked jointly in manufacturing).

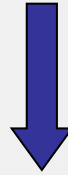
³⁾ See Annex B example sheet when manufacturing materials.

The practical cycle with the help of the guideline

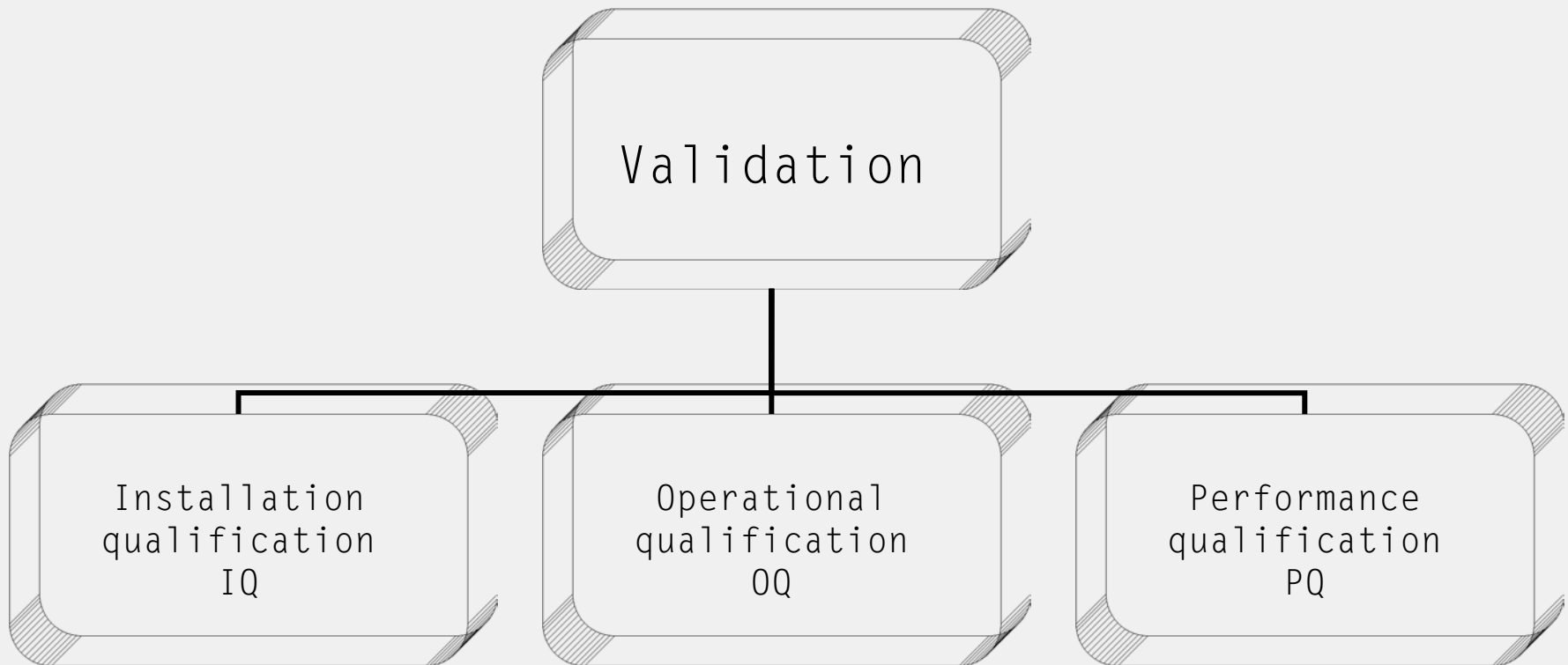
- Requirements
- Drafting of a validation plan
- **Conduct of validation**
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation

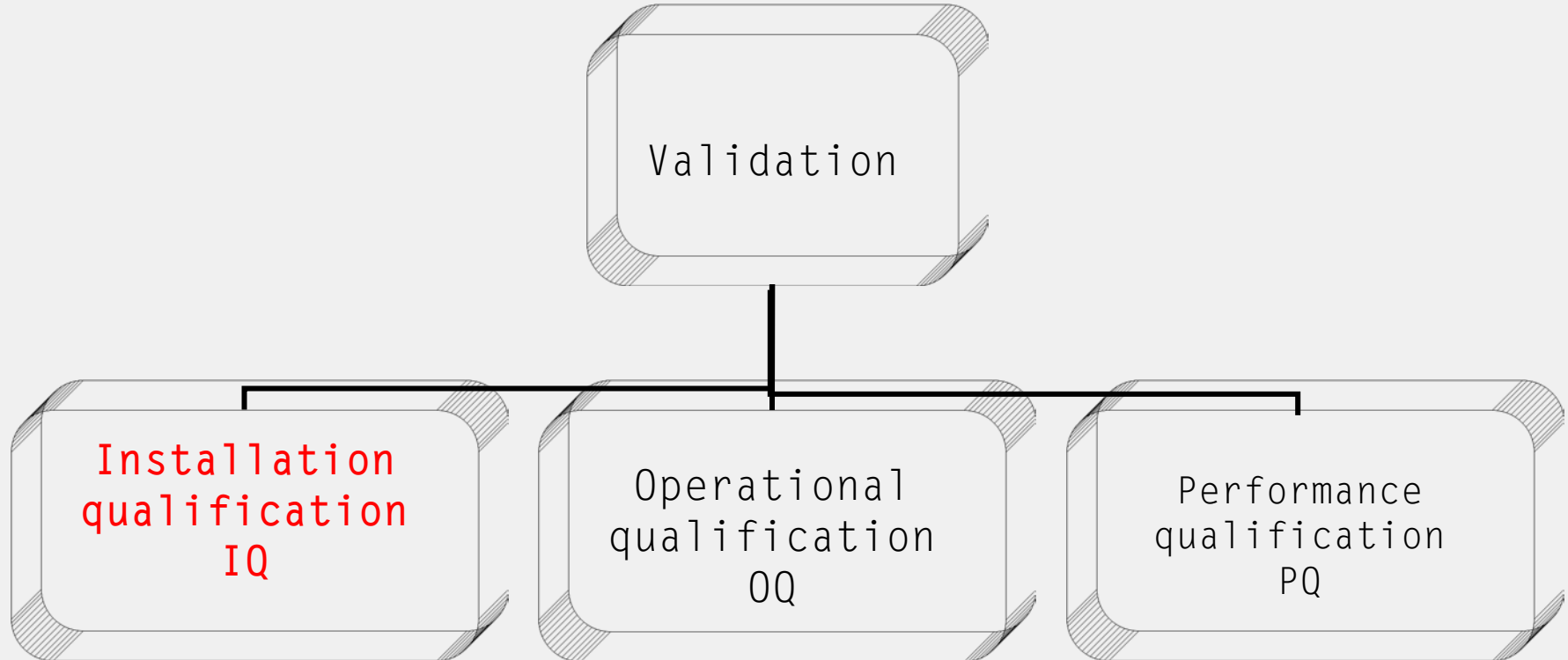


Sterilization sheets folding and wrapping



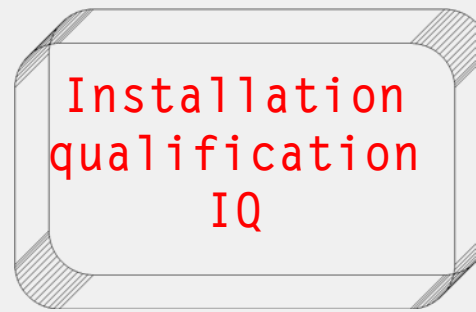
Process validation in 3 steps





Definition:

„Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the specification.“

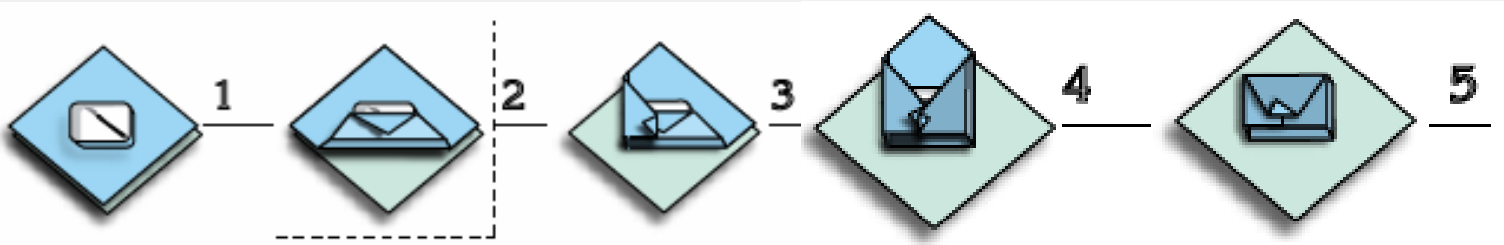


- Technical equipment must have been properly installed
- Users/staff must have been trained and standard operating procedures are known (documentation of training of staff)

Standard operating procedures?

Installation qualification
IQ

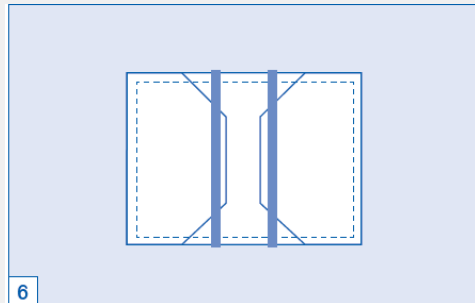
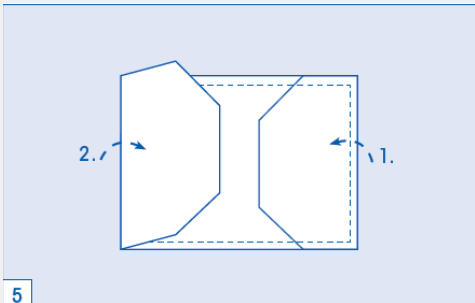
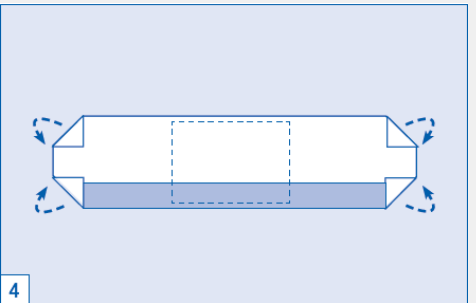
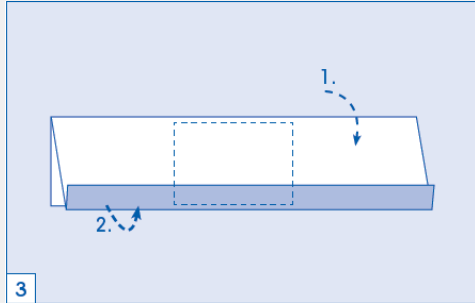
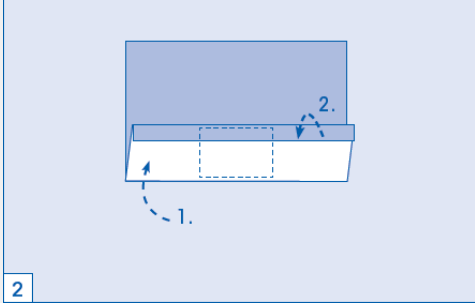
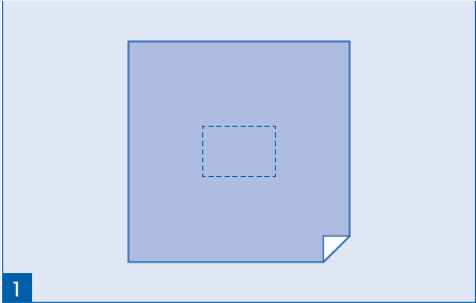
Diagonal packaging



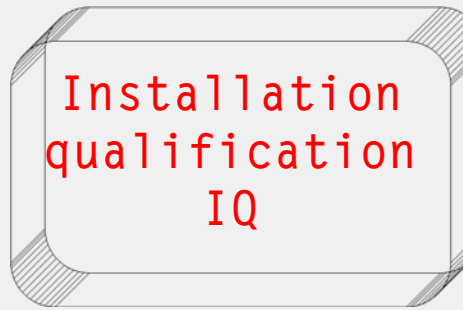
Standard operating procedures?

Installation
qualification
IQ

Parallel packaging:



Installation qualification (IQ) checklist



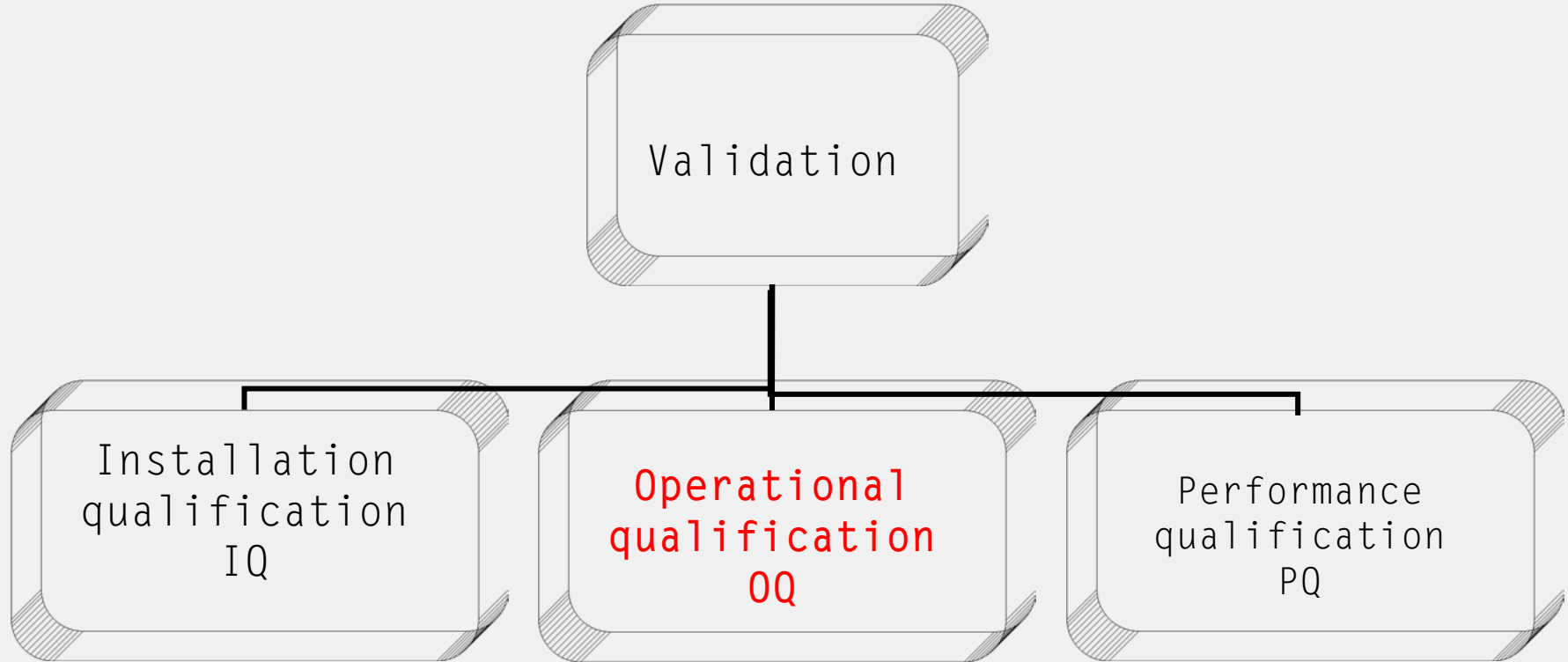
Annex B.2 : Installation qualification (IQ) checklist «sterilization sheets' folding and wrapping»

Are standard operating procedures available (SOPs)? (e. g. as in Annex B.5)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Where? _____
--	------------------------------	-----------------------------	--

I a) Training

Name of trained staff member	Training			Signature	
	By	Qualification	Date	Trainer	Trainee

Only if all users are inducted/trained will Installation qualification be deemed to have been passed.



Definition:

„Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.“

Operational
qualification
OQ

- Packaging systems –
 - sterile barrier systems and
 - packaging materials
- double checking of the quality properties is necessary

Number of samples: 10
(photographic documentation)

- Continuous closeness/integrity
- No punctures or tears
- No other visible damage or material irregularities

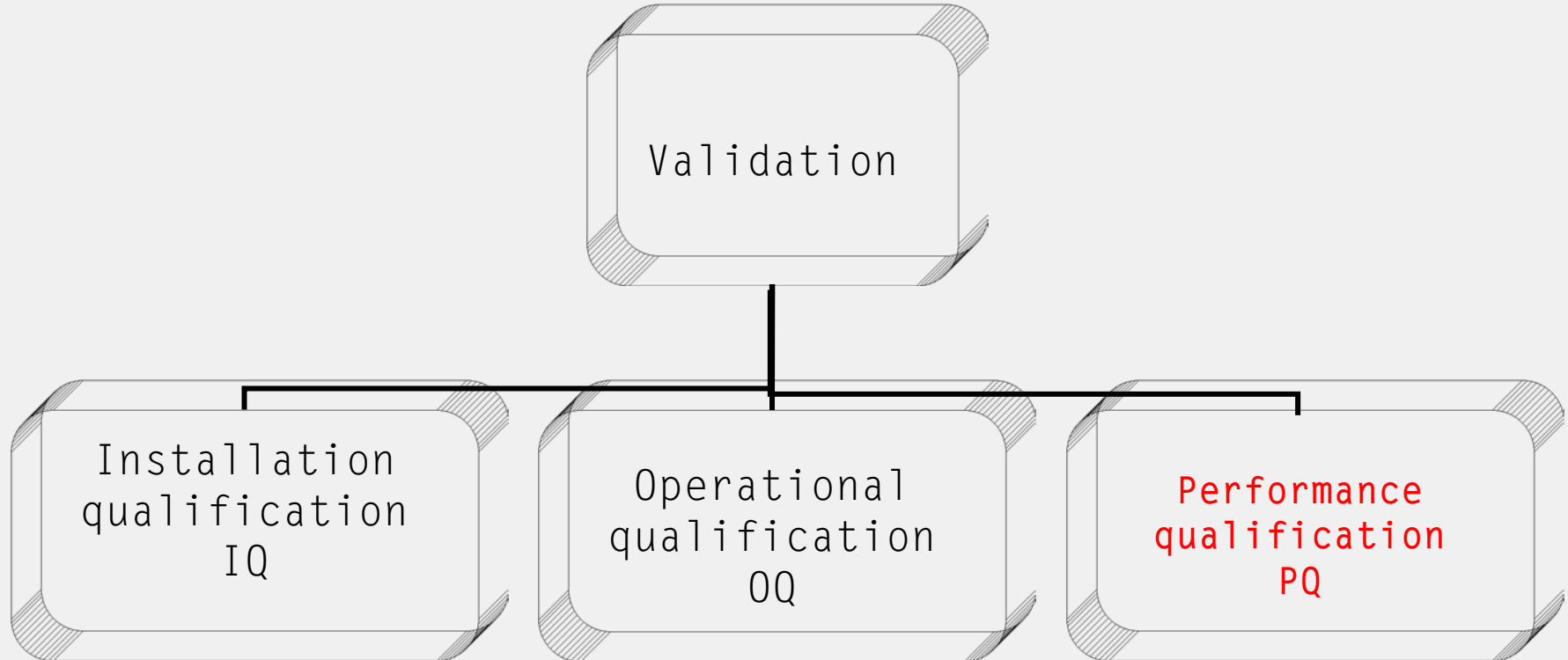
Operational qualification OQ

Annexe B.3 : Operational qualification (OQ) checklist «sterilization sheets' folding and wrapping»

If the packaging system is composed of a sterile barrier system and protective packaging, the quality properties of both the sterile barrier system and protective packaging have to be verified for OQ.

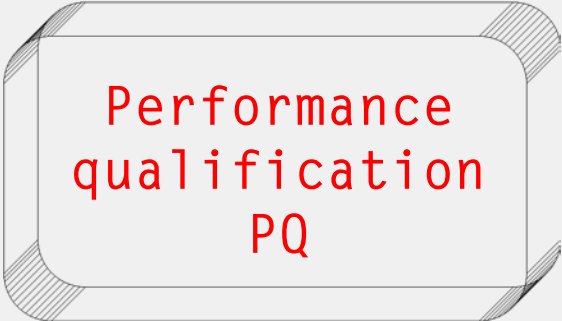
Requirement for sample size (S) ²		S ≥ 10	
Sample size (S)		S =	
Compliance with requirement	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Quality properties		Compliance	
Intact closeness/integrity		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Evidence based on			
Test method: _____		Name/signature _____	
No punctures (perforation) or tears	Protective packaging		Sterile barrier system
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Evidence based on			
Test method: _____		Name/signature _____	
No other visible damage or material irregularities	Protective packaging		Sterile barrier system
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Evidence based on			
Test method: _____		Name/signature _____	

To document the quality properties, it is recommended that at least one photo be taken in addition of each sample.



Definition:

„Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.“

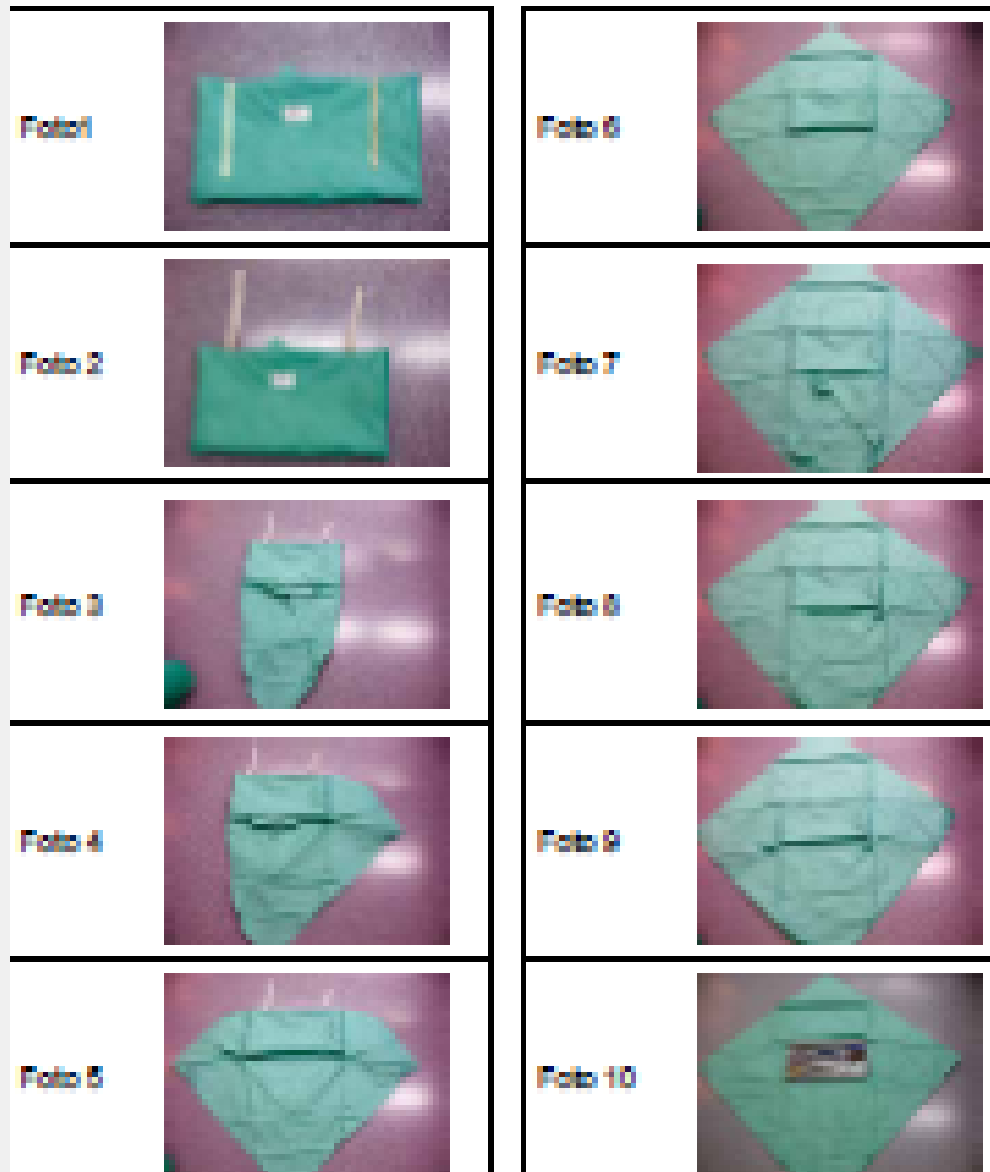


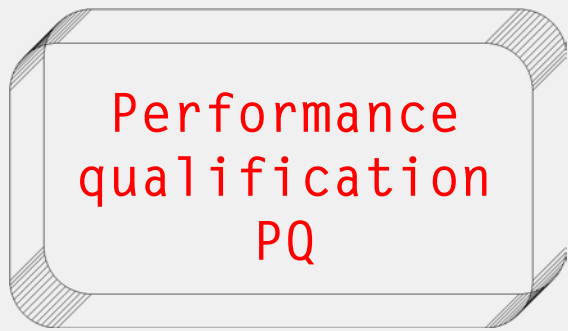
Performance
qualification
PQ

- Sterilized packaging systems must be taken from the running processes
- From 3 different cycles (batches) one sample must be taken in each case
- Assurance of the quality must be verified for each packaging
- Compliance with the defined packaging techniques
- Photographic documentation

Photographic documentation:

Opening step by step «sterilization sheets»





Annex B.4 Performance qualification (PQ) check list validation sheeta.Följande övervaknings

Criteria	Batch I/A		Batch B/B		Batch C/C	
	Yes	No	Yes	No	Yes	No
Describe the qualification						
Activities performed/validity and version (status sequence confirmed)						

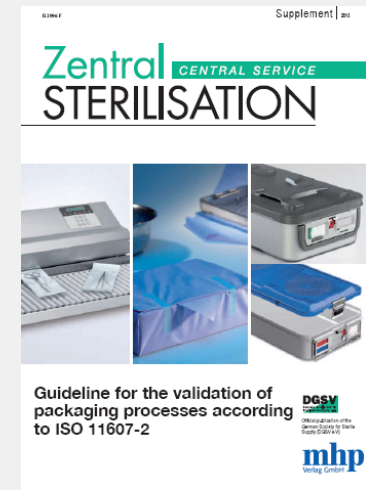
Cycle test A: quality properties	Group I/II	
Insert substances/fragility	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Endorse based on Närstämplat vär	
What next test:	
Do you receive (per finished) warnings	Preventive packaging	Bar/for term/inspektions
Endorse based on	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Is an identifiable damage, contamination, material irregularities or residual moisture	Preventive packaging	Bar/for term/inspektions
Endorse based on visual inspection	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Compliance with defined packing max load (EN 8943-7 Annex A.1)	Preventive packaging	Bar/for term/inspektions
Endorse based on ph. stographic documents taken	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	

Cycle test B: quality properties	Group I/II	
Insert substances/fragility	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Endorse based on Närstämplat vär	
What next test:	
Do you receive (per finished) warnings	Preventive packaging	Bar/for term/inspektions
Endorse based on	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Is an identifiable damage, contamination, material irregularities or residual moisture	Preventive packaging	Bar/for term/inspektions
Endorse based on	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Compliance with defined packing max load (EN 8943-7 Annex A.1)	Preventive packaging	Bar/for term/inspektions
Endorse based on ph. stographic documents taken	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	

Cycle test C: quality properties	Group I/II	
Insert substances/fragility	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Endorse based on Närstämplat vär	
What next test:	
Do you receive (per finished) warnings	Preventive packaging	Bar/for term/inspektions
Endorse based on	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Is an identifiable damage, contamination, material irregularities or residual moisture	Preventive packaging	Bar/for term/inspektions
Endorse based on	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	
Compliance with defined packing max load (EN 8943-7 Annex A.1)	Preventive packaging	Bar/for term/inspektions
Endorse based on ph. stographic documents taken	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
What next test:	

The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- **Drafting of a validation report**
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation



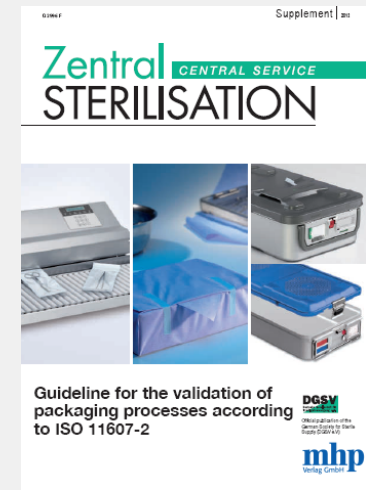
Drafting of a validation report

Content of the validation report:

- Validation plan
- Evidence of implementation of the validation plan (IQ, OQ, PQ checklists)
- Evaluation of the results
- Photographic documentation for manual packaging processes
- Details and explanation of any deviations from validation plan
- Formal approval of validation
- Process control and monitoring
- Process changes and revalidation

The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- **Formal approval of the validation process**
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation



Formal approval of the validation process

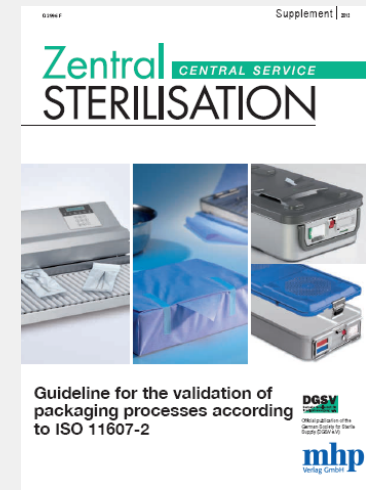
Validation must be formally approved and duly documented by the competent person appointed by the operator

- Therefore a field is provided in the validation plan

! Clear documentation of not accepted results including assessment of any remaining risks

The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- **Process control and monitoring**
- Process changes and revalidation
- Table of the process validation



Process control and monitoring

One result of the validation –
Necessary routine tests for on time recognition
of changes in the packaging process

Preservation of the
requirements of the sterile
barrier systems


Process control and monitoring

e.g. in standard operating procedures

Routine tests are for example:

- Visual inspections
- Stepwise opening of packaging

Definition of

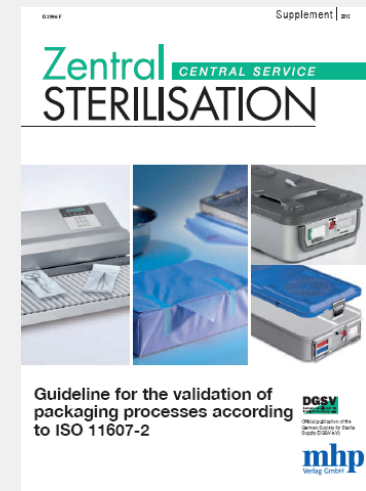
 Intervals of conducting the routine tests (e.g. daily, weekly, monthly, yearly, ...)

 Acceptance values

 Way of the documentation

The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- **Process changes and revalidation**
- Table of the process validation



Process changes and revalidation

Unscheduled Revalidation:

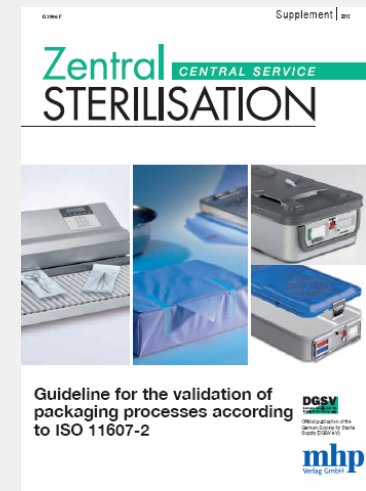
- e.g. in the event of changes to
 - Materials
 - Processes
 - Sterilization

Scheduled Revalidation:

- If there are no changes
- 🕒 at regular intervals, general after one year

The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- **Table of the process validation**



Validation of packaging processes: sterilization sheets´ folding and wrapping

How is the amount of necessary checks measured?

Table of the process validation

Packaging	STEAM			FORM (formal- dehyde)	EO (ethylene oxide)	VH2O2 (plasma)
	134 °C/5 min	134 °C/18 min	121 °C/20 min			
Material A (crepe paper)	x	x*	x			
Material B (nonwovens)	x	x*	x	x*		
Material C (SMS nonwovens)	x	x*	x	x*		x*
Material D (textile materials)	x*					

The 13 combinations outlined in the table can be reduced by taking account of only the maximum material stress (worst-case scenario, while providing documentary proof to justify this; in this example for material A, B and C: 134 °C/18 min). These combinations are marked with an x* in the table. This shows that in this example validation needs to be carried out in total seven times. A further reduction can be achieved by a deliberate sterile barrier system (e. g. by using only two different materials). Accordingly, for this example the number of validations would be reduced from seven to five or even four.

Note: When using packaging sheets for FORM or EO sterilization one must ensure that the maximum residual content of sterilant permitted is not exceeded.

- **This was an example of the validation of a manual packaging process.**
- **The process for the validation of containers and pouch, reel and bag sealing have the same structure**

The purpose of our work:

For operators and all persons related to medical device reprocessing:

- Showing the possibility to validate the total packaging process**
- Providing a practical orientation guide for a validation according to DIN EN ISO 11607-2**

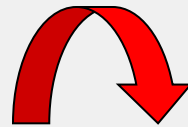
Purpose of this guideline

This guideline supports ...

- ➔ ... in structuring processes
- ➔ ... in optimizing internal processes
- ➔ ... the control and monitoring of processes
- ➔ ... the Management of sterilization departments in their preparations

The purpose of our work:

- Approaching a uniform comprehension for operators, validators, supervisory authorities and certification bodies
- Uniform and correct conduction of the validation of packaging processes



Not at least to avoid confusion!

Thank you for your
attention!

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