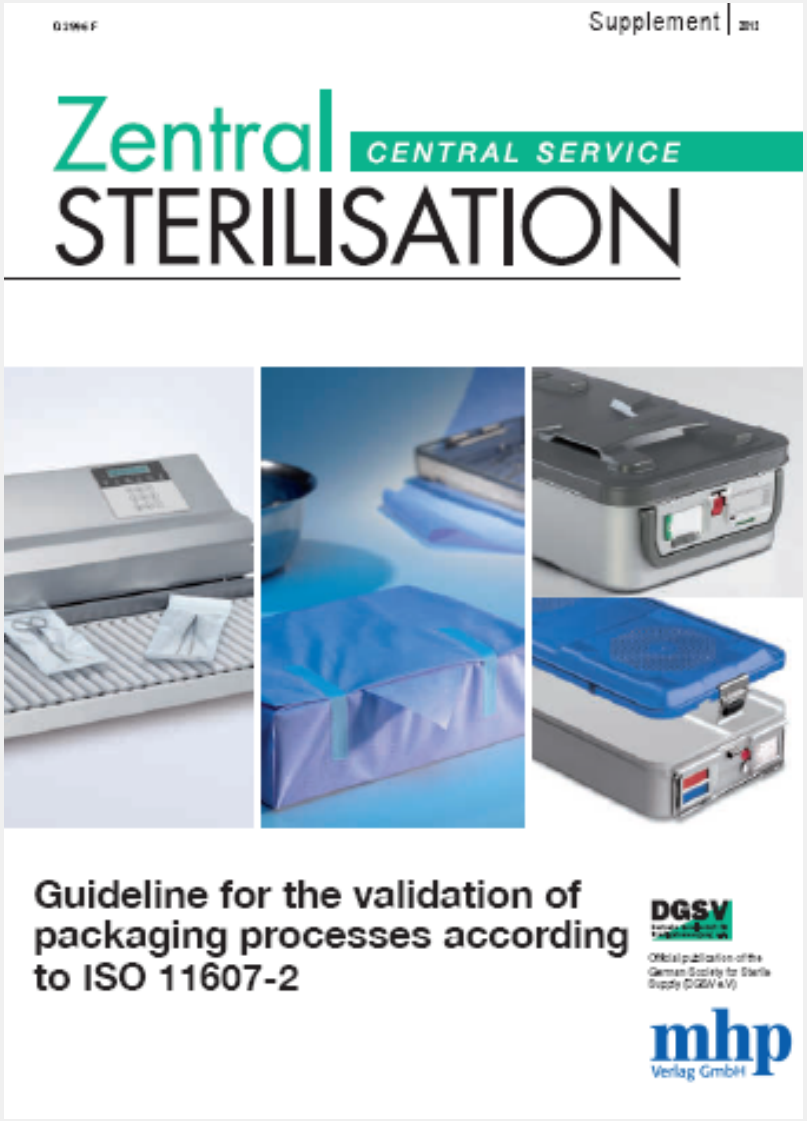
Guideline for the validation of packaging processes according to DIN EN ISO 11607-2



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 devises as well as users, e.g.:
  - Gluing of packages
  - Materials which are difficult to handle
  - Poor quality of adhesive tape
  - …

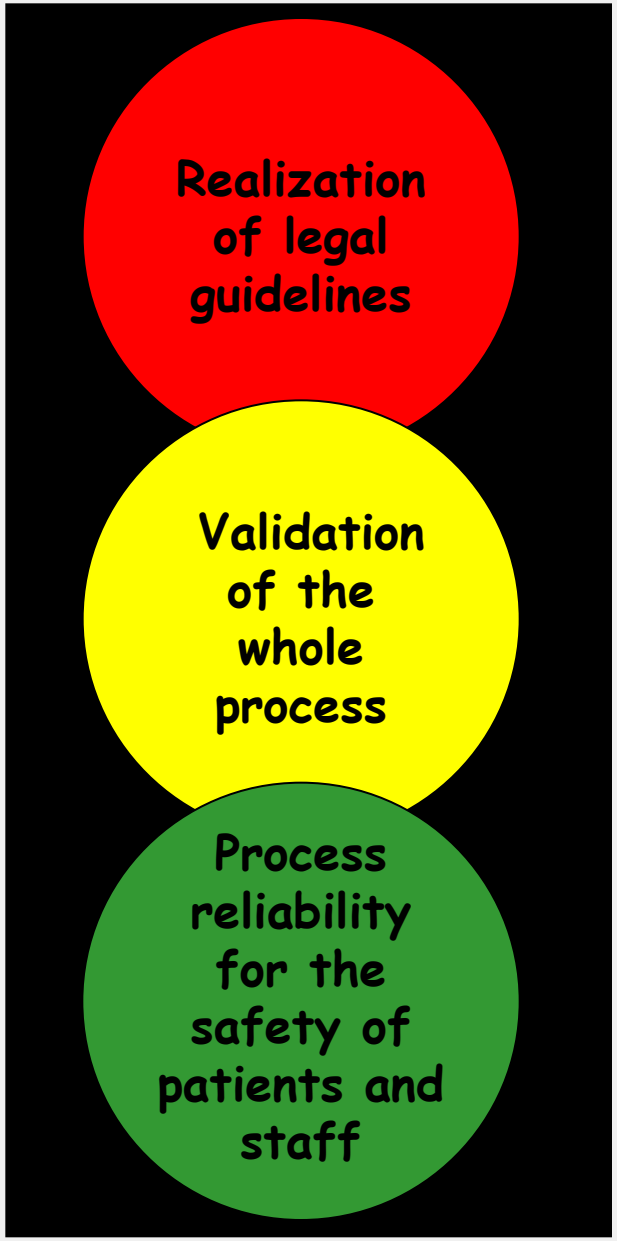
The work group's perspective:

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

Yes - 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?

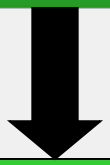
- ✓ **Manual cleaning and disinfection processes**

  Visual inspection
  Maintenance process
  Operational qualification

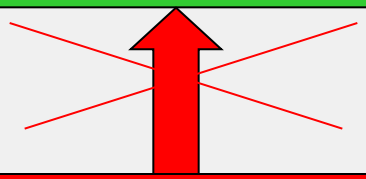
- ✓ **Packaging of medical devices in pouches, reels and bags**
- ✓ **Soft packaging (Sterilization sheet's folding and wrapping)**
- ✓ **Container packaging (reusable container)**

  Approval

➔ **Storage and transport**



Basis for a validation or rather always comprehensible and reproducible processes



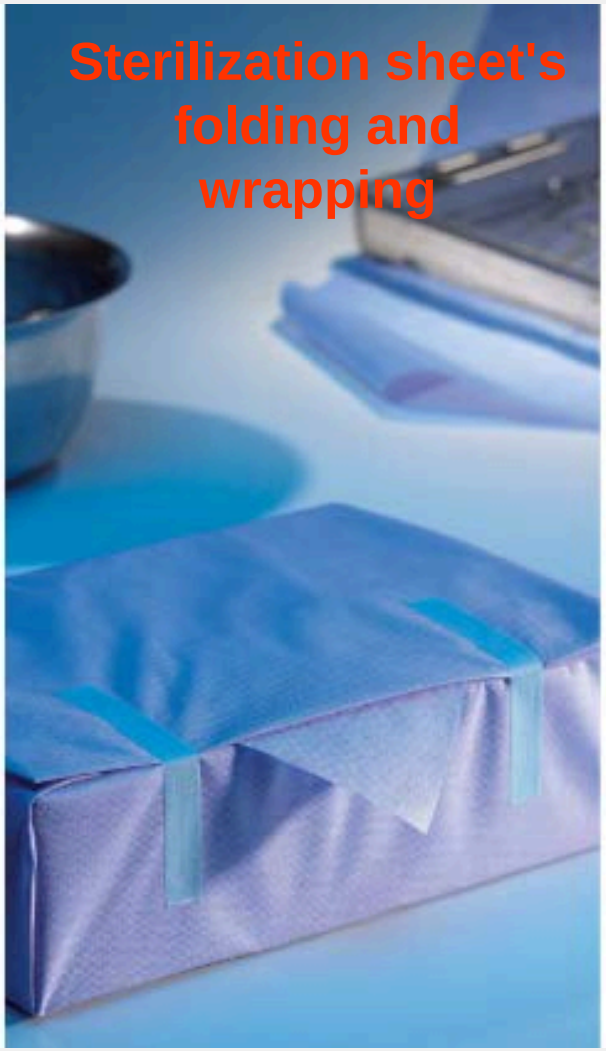
<u>Without a Quality Management System</u>
a validation is not possible. All steps have to be defined and documented.

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



Validation using the example of the following packaging process:

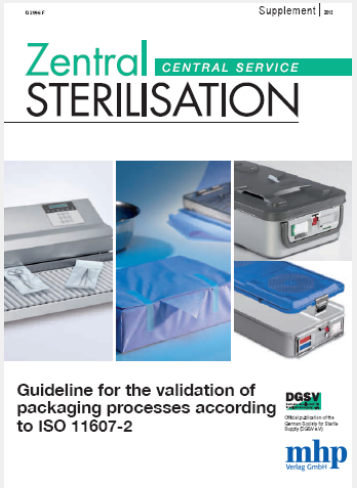
Folding and wrapping of sterilization sheets

Initial validation

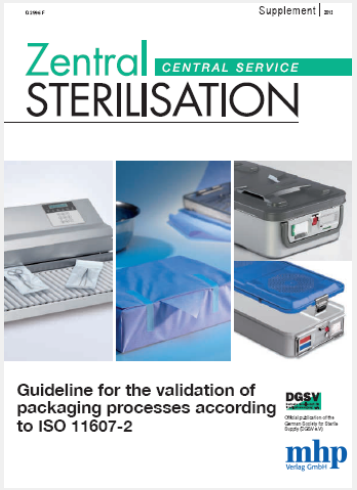
- Initial operating

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



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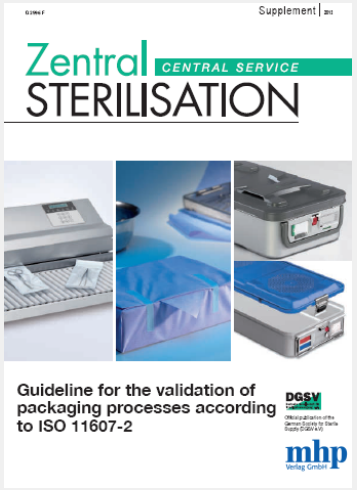
Requirements

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



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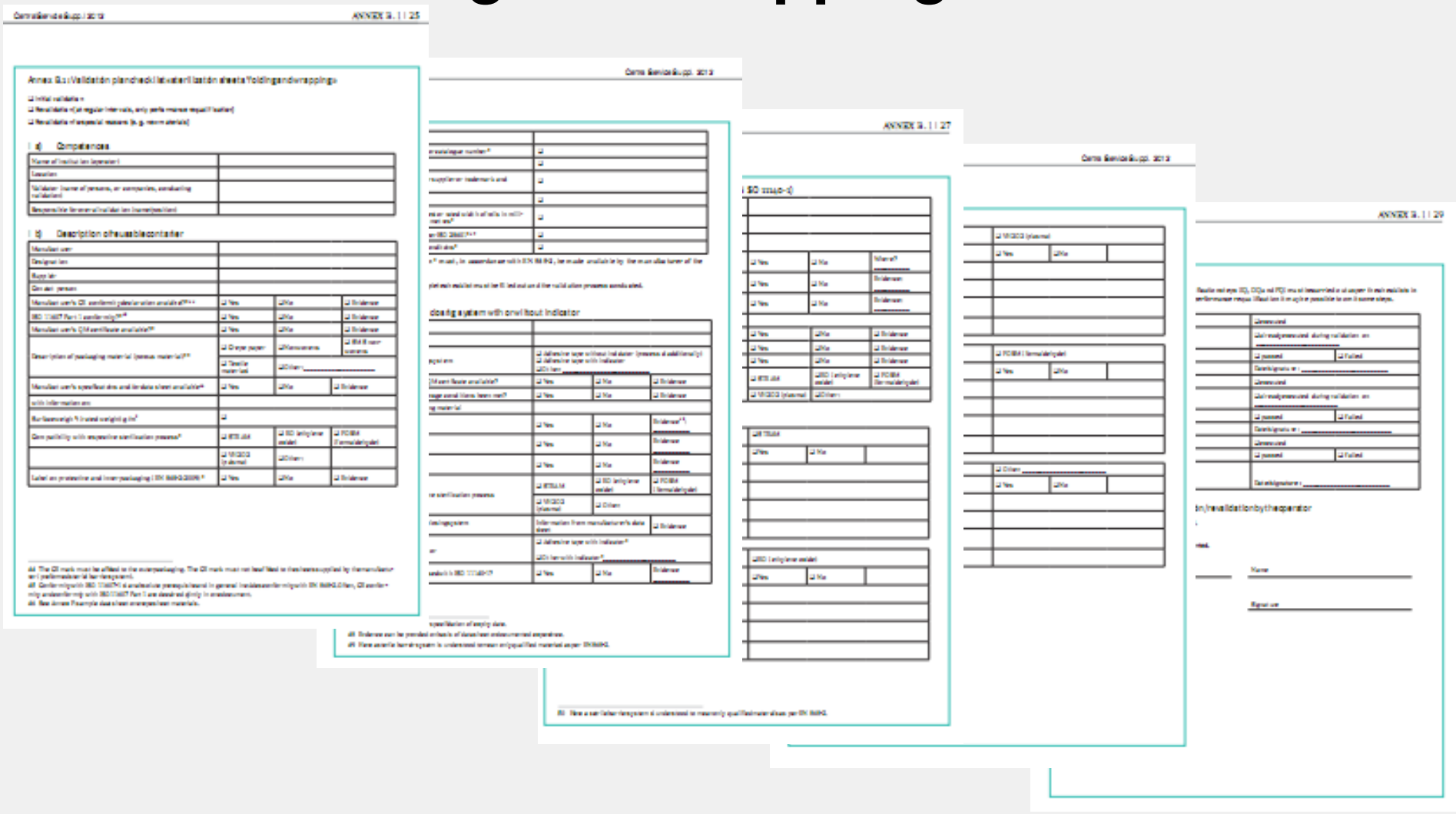
Drafting of a validation plan

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“



Annex 8.1: Validation plan checklist validation sheets Folding and wrappings

☐ Initial validation
☐ Revalidation (at regular intervals, only performance requalification)
☐ Revalidation for special reasons (e.g. new materials)

I a) Competences

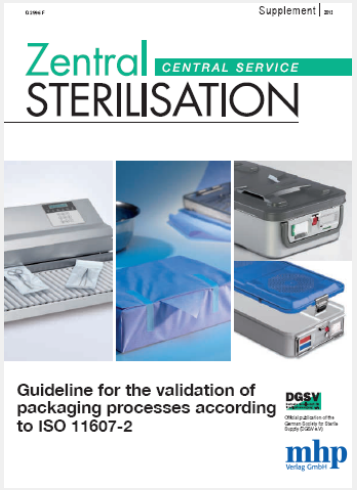
Name of institution (operator)	
Location	
Validator (name of persons, or companies, conducting validation)	
Responsible for overall validation (name/position)	

I b) Description of reusable container

Manufacturer			
Designation			
Supplier			
Contact person			
Manufacturer's CE conformity declaration available?	☐ Yes	☐ No	☐ Evidence
ISO 11607 Part 1 conformity?	☐ Yes	☐ No	☐ Evidence
Manufacturer's QM certificate available?	☐ Yes	☐ No	☐ Evidence
Description of packaging material (sterile material?)	☐ Crepe paper	☐ Nonwovens	☐ SMS nonwovens
	☐ Textile material	☐ Other: ______________	
Manufacturer's specification and/or data sheet available?	☐ Yes	☐ No	☐ Evidence
with information on:			
Surface weight / basis weight g/m²	☐		
Compatibility with respective sterilization process?	☐ STEAM	☐ EO (ethylene oxide)	☐ FORM (formaldehyde)
	☐ H2O2 (plasma)	☐ Other:	
Label on protective and inner packaging (EN 868-2:2009)?	☐ Yes	☐ No	☐ Evidence

[illegible]

The practical cycle with the help of the guideline



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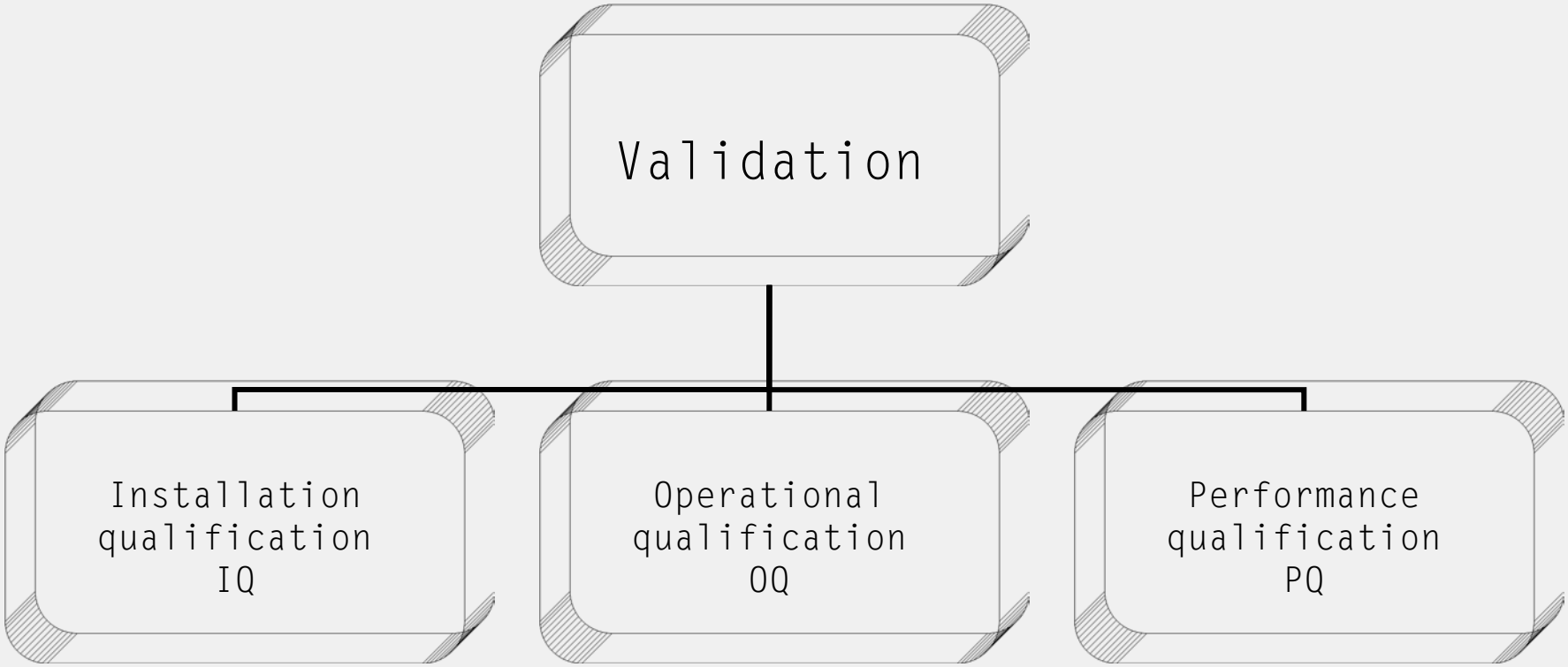
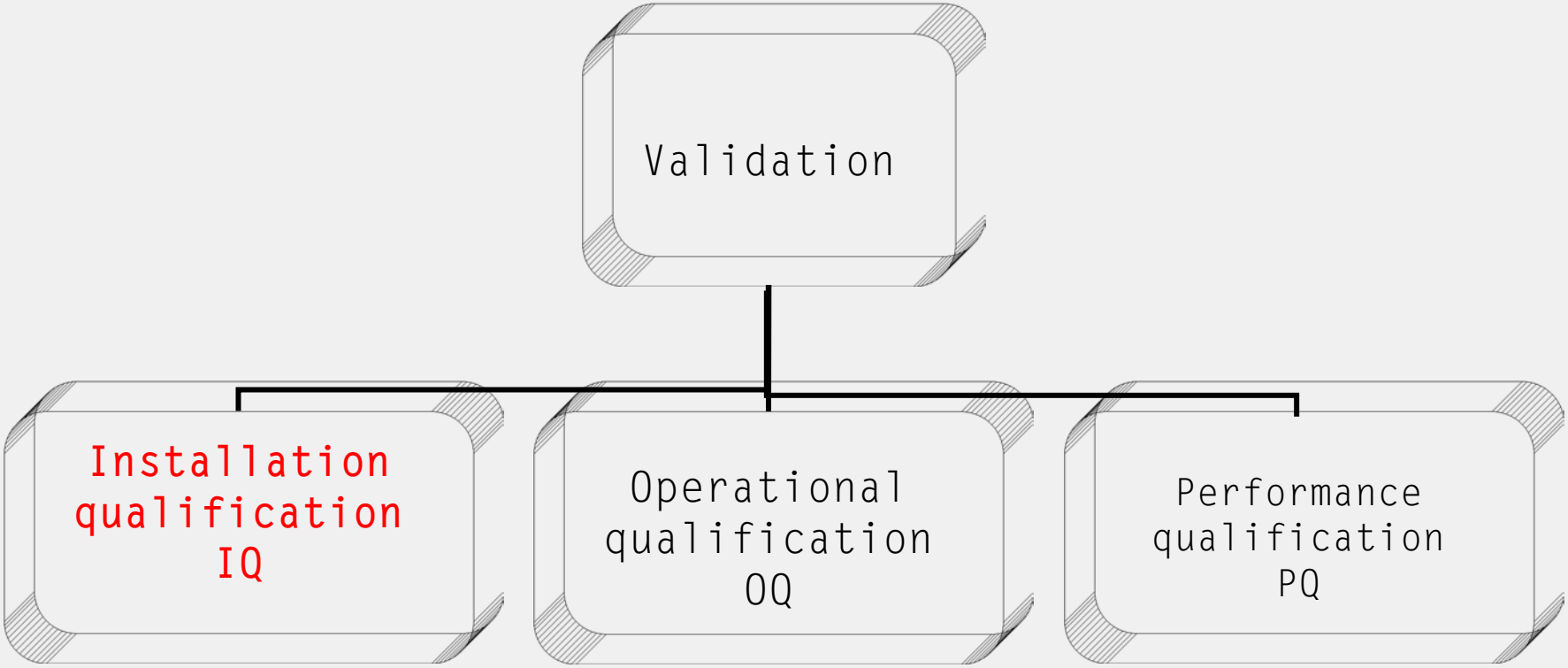
Sterilization sheets folding and wrapping

Process validation in 3 steps





Definition:

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

Installation qualification IQ

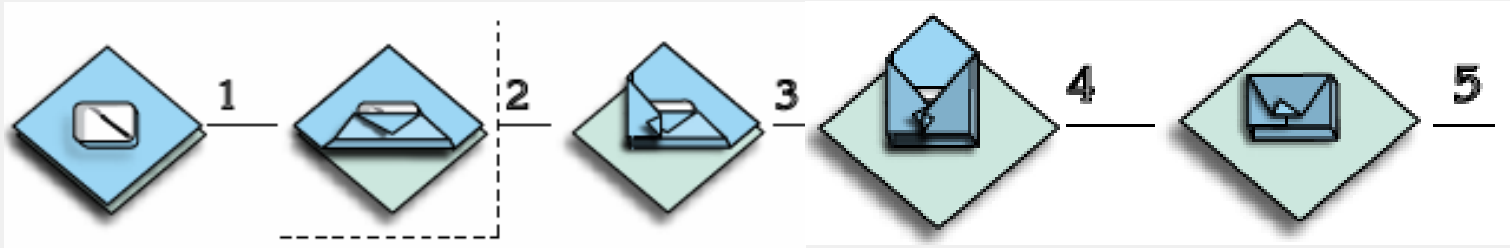
- Technical equipment must have been properly installed

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

Standard operating procedures?

Installation qualification IQ

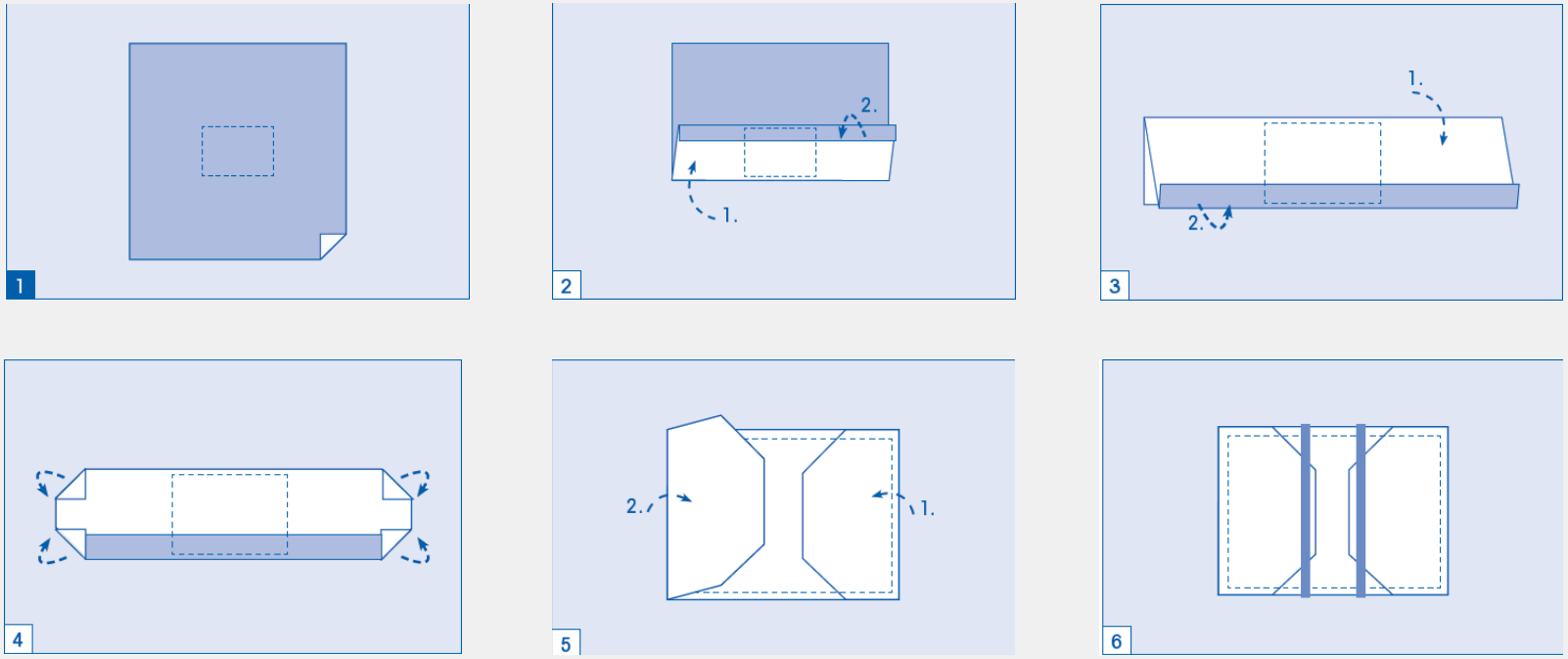
Diagonal packaging



Standard operating procedures?

Installation qualification IQ

Parallel packaging:



Installation qualification (IQ) checklist

Installation qualification IQ

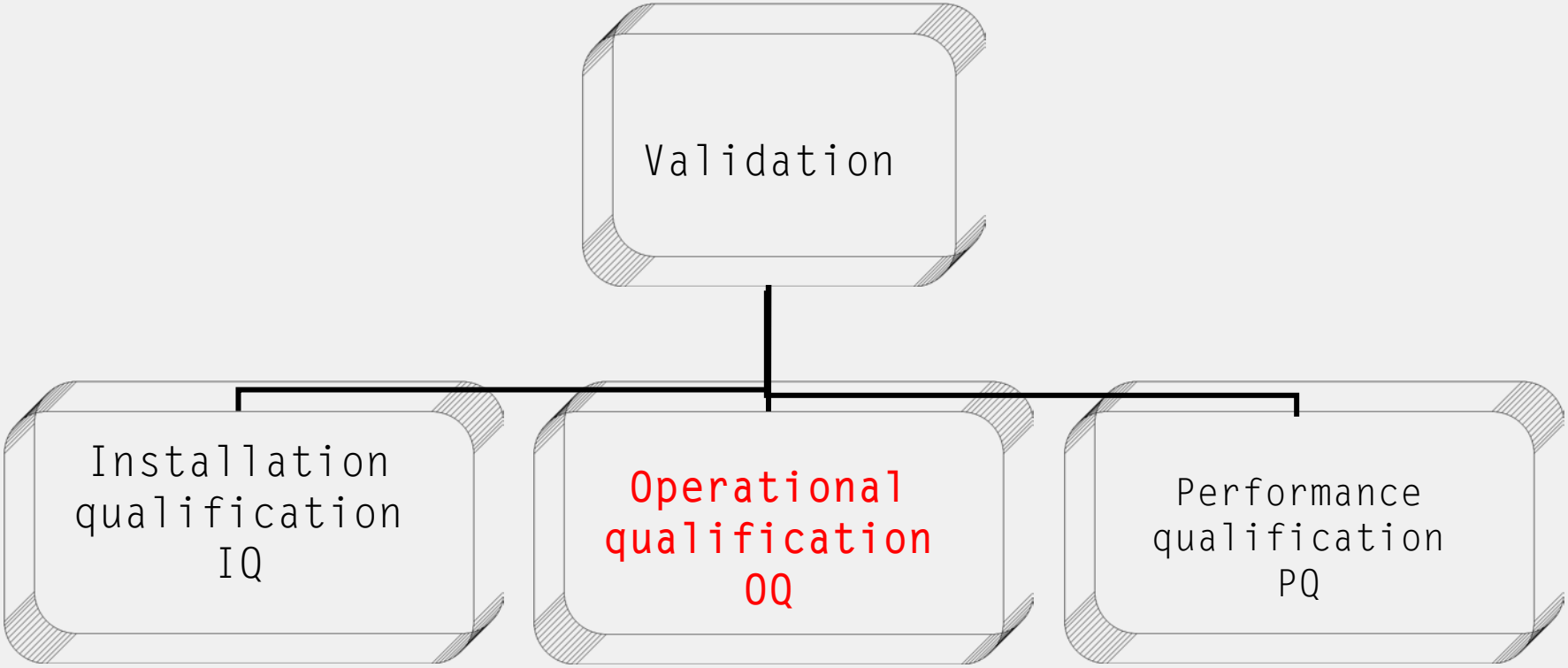
Annex B.2 : Installation qualification (IQ) checklist «sterilization sheets' folding and wrapping»

Are standard operating procedures available (SOPs)? (e. g. as in Annex B.6)	❑ Yes	❑ No	❑ 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

Operational qualification OQ

Number of samples: 10

(photographic documentation)

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

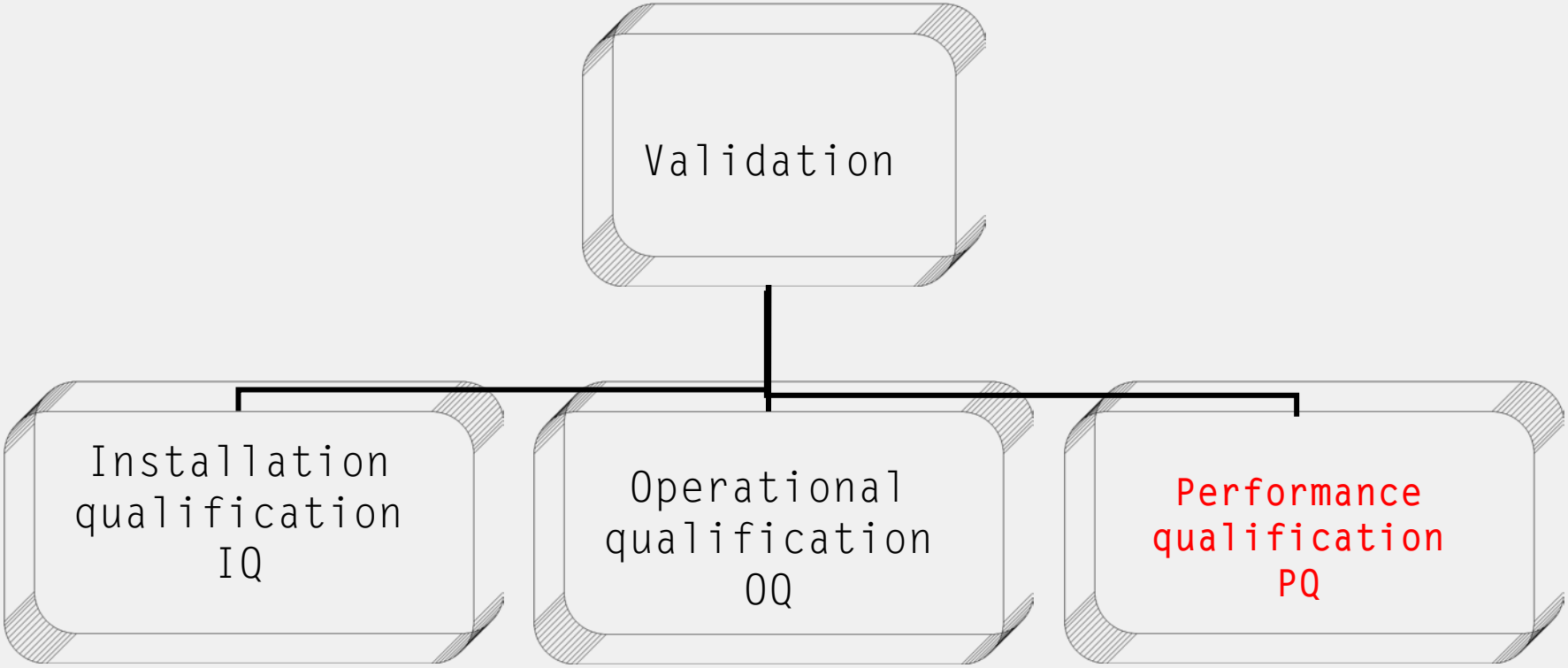
Operational qualification OQ

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)[a]			S ≥ 10	
Sample size (S)			S =	
Compliance with requirement	❑ Yes	❑ No		
Quality properties			Compliance	
Intact closeness/integrity			❑ Yes	❑ No
Evidence based on Test method: _____			_____ Name/signature	
No punctures (perforation) or tears			Protective packaging ❑ Yes ❑ No	Sterile barrier system ❑ Yes ❑ No
Evidence based on Test method: _____			_____ Nom/signature	
No other visible damage or material irregularities			Protective packaging ❑ Yes ❑ No	Sterile barrier system ❑ Yes ❑ 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."

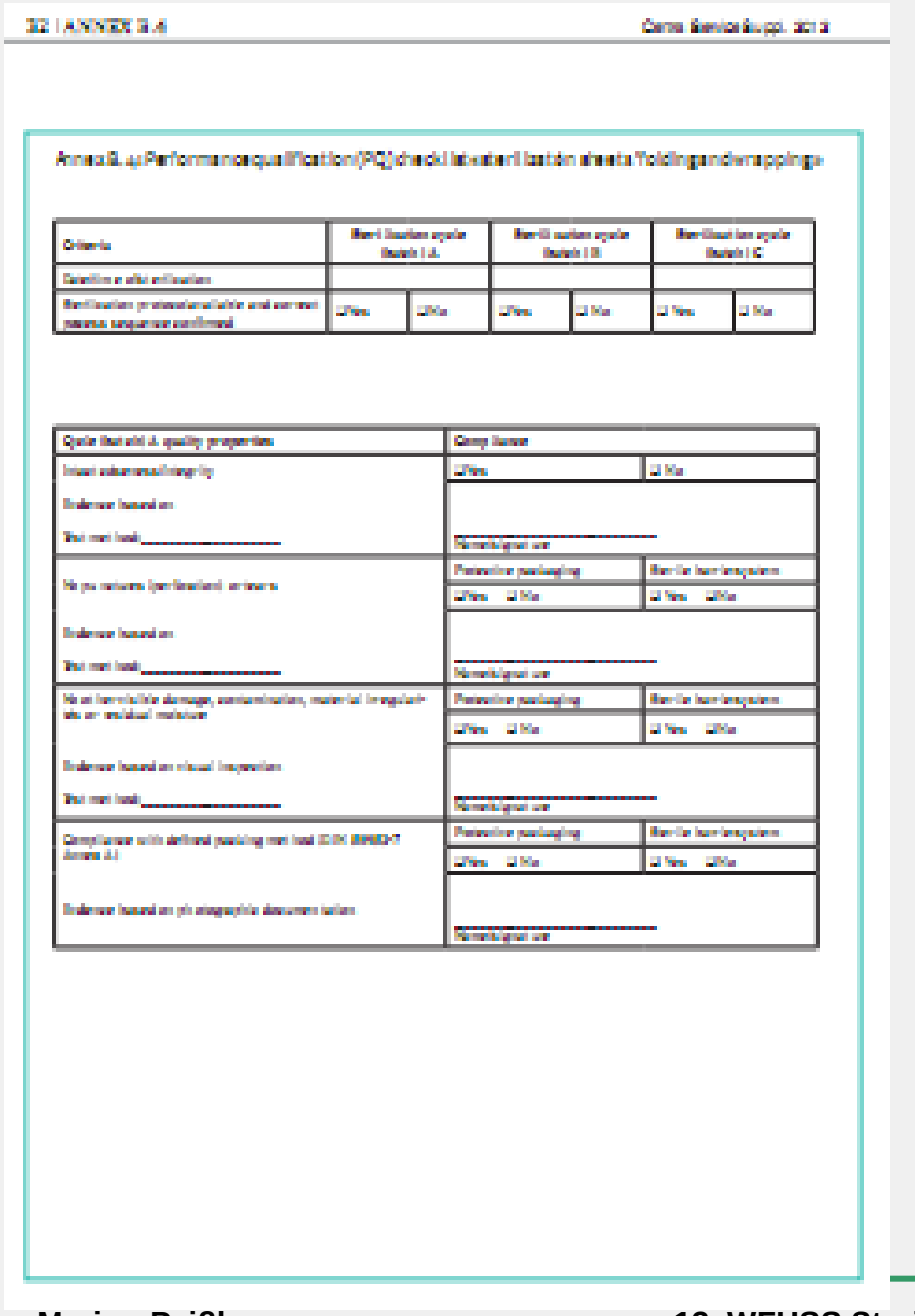
Performance qualification PQ

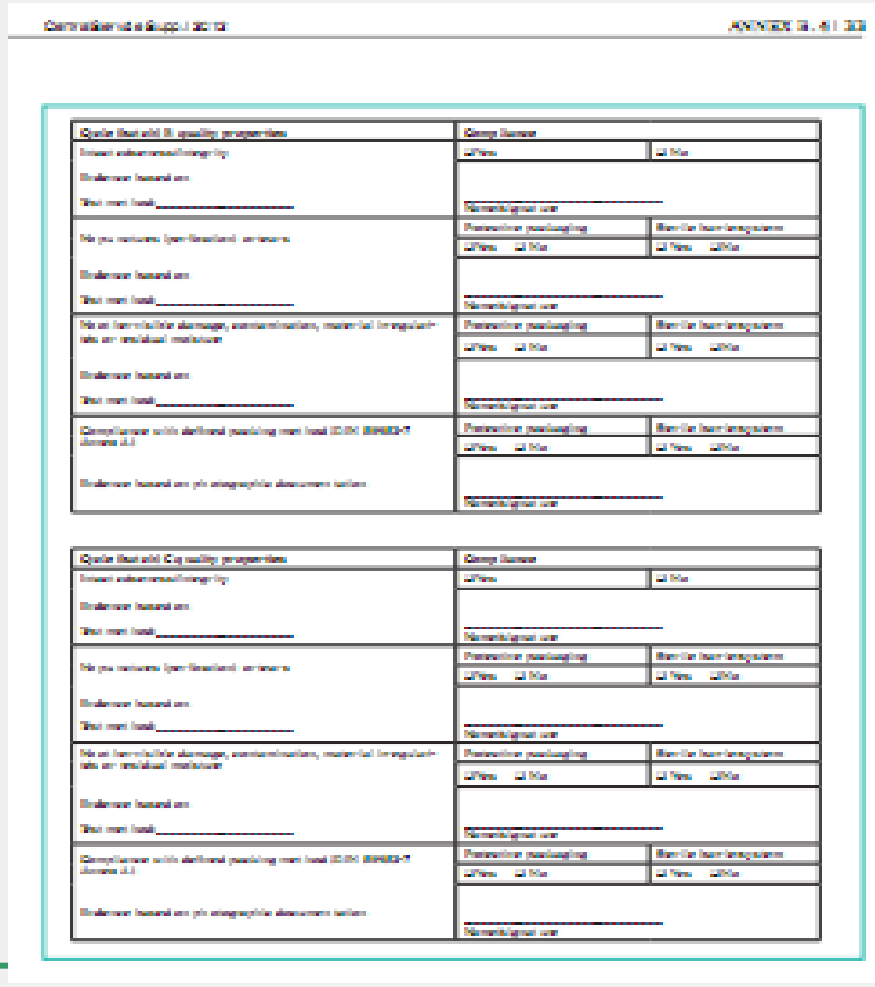
- Sterilized packaging systems must be taken from the running processes
- From 3 different cycles (batches) one sample must be taken in each case
- Assurance of the quality must be verified for each packaging
- Compliance with the defined packaging techniques
- Photographic documentation

Photographic documentation:

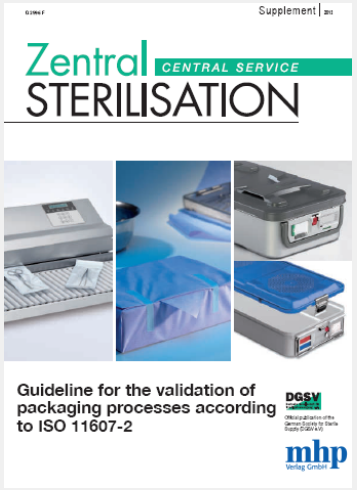
Opening step by step «sterilization sheets»

Performance qualification PQ





The practical cycle with the help of the guideline



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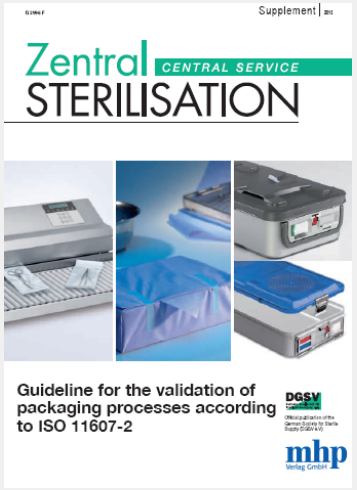
- ➔**Process changes and revalidation**
- ➔**Table of the process validation**

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



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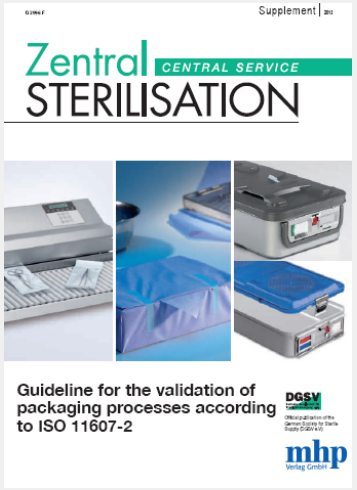
Formal approval of the validation process

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



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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

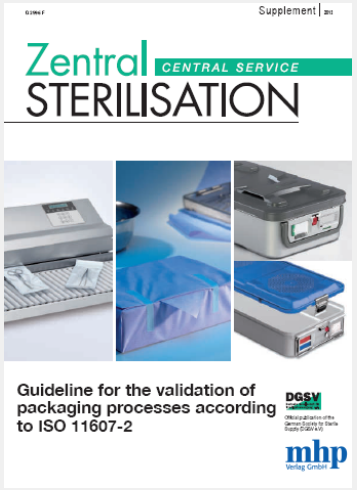
Routine tests are for example:

- 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



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Process changes and revalidation

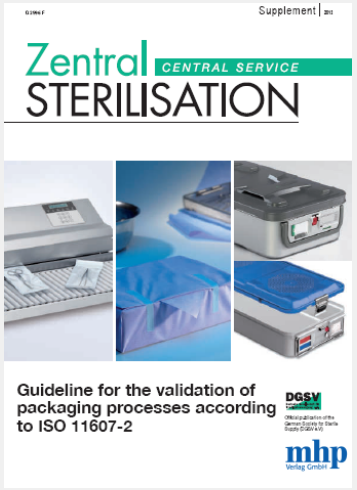
Unscheduled Revalidation:

- 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



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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)	×	×*	×			
Material B (nonwovens)	×	×*	×	×*		
Material C (SMS nonwovens)	×	×*	×	×*		×*
Material D (textile materials)	×*					

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 ×* 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

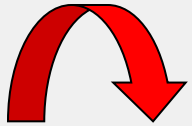
➔… the control and monitoring of processes

➔… 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!
Marion-Peissker@web.de