Validation in healthcare

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Introduction

- Why?
- What?
- How?
- When?
- Who?

What is validation?

- Definition according to ISO15883, ISO17665, EN285:

  documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification

Translation:

- Specify your criteria you want to meet/fulfil
- Gather information: documents, measurements, tests, observations
- Interpreted the gathered information to the specified criteria

Less appropriate reasons for validations

- Inspection of government
- Quality system
- Accreditation
- To fulfil requirements in norms

- These reasons could be tools to take corrective measures
- More or less fake reasons

Appropriate reason: Patient care

- A patient want to be cured in an hospital
- An hospital claims to work with sterile medical devices
- An hospital works needs to work with sterile medical devices
- The hospital is responsible for the medical devices
- The responsibility cannot be taken over or delegate
- The hospital has to able to prove that it is working with sterile medical devices

Why is validation not always performed

- Machine is too old
- A very good machine so not necessary
- Responsible person is not completely informed about what validation is
- Responsible person is not aware of the working of machinery

Why validation is performed:

- To prove your claim

In health care:

- For the benefit of the patient, staff and environment
- A validation is an insurance for the hospital and patient

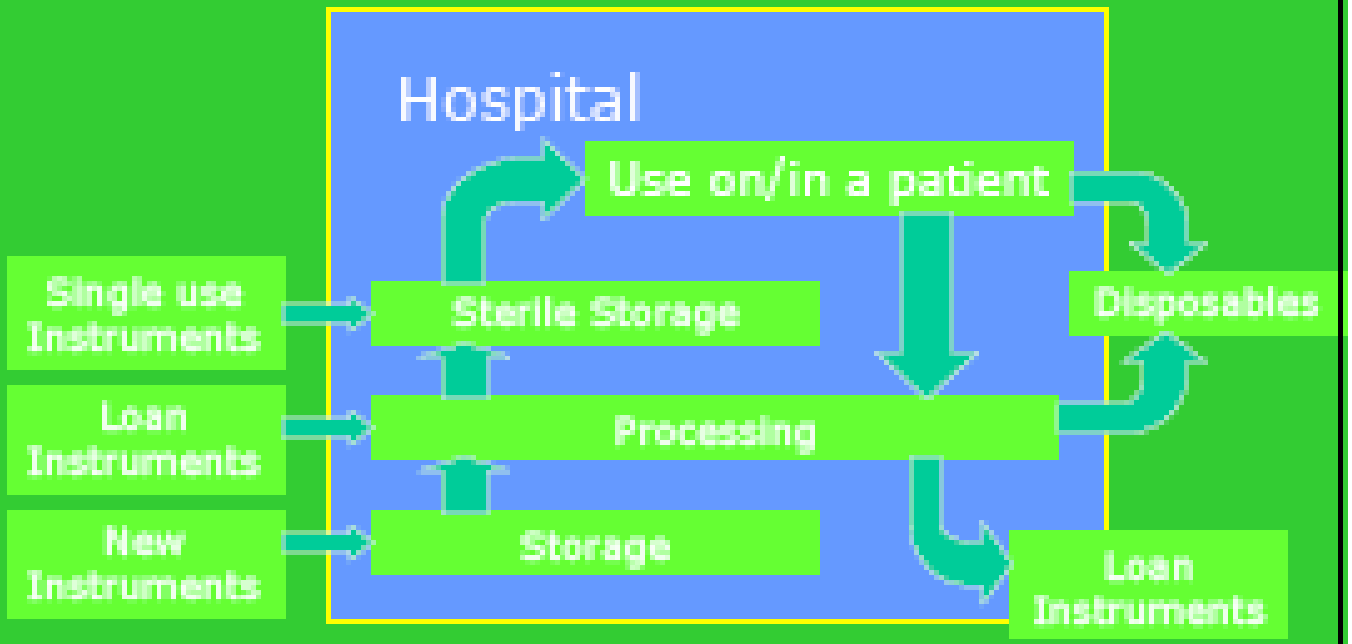
Hospital setting

- Reprocessed sterile medical devices
- All moments of decontamination (washing, disinfecting and sterilization)

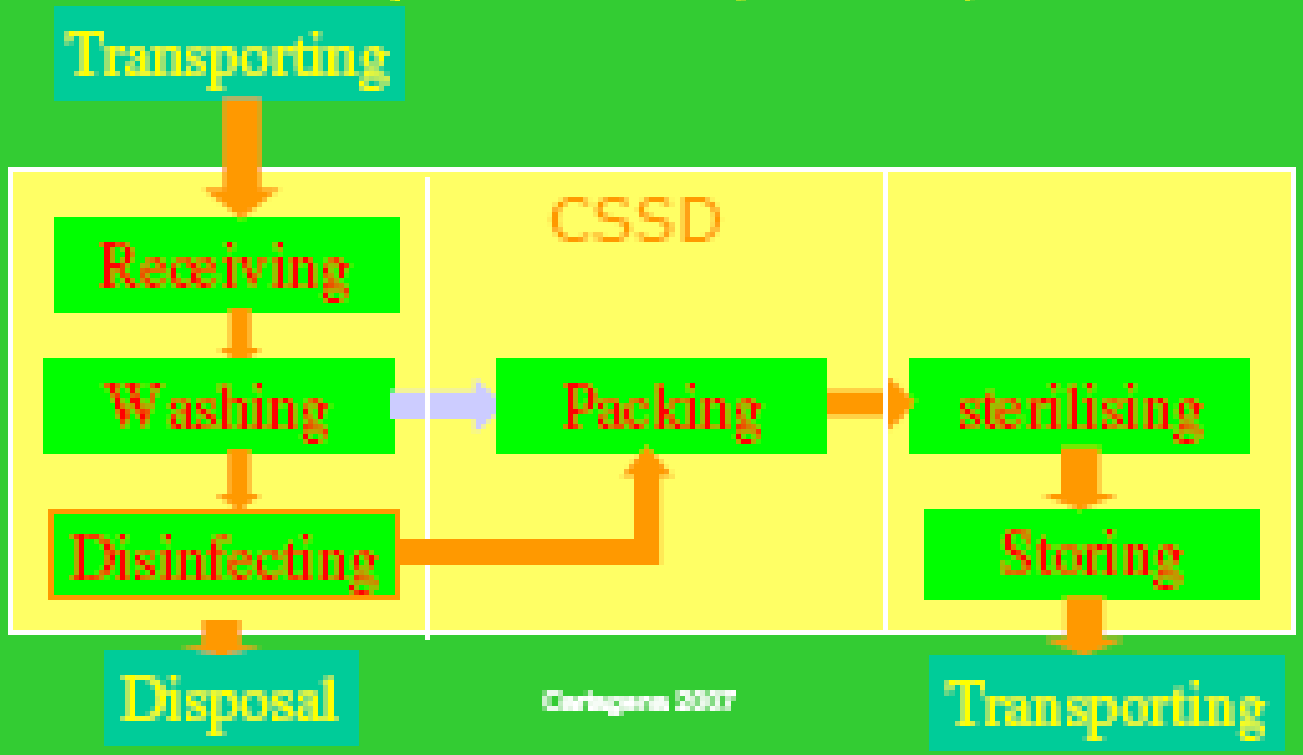
What to validate

- Rinsing/washing
- Washing/disinfecting
- Sterilizing

Routing in an Hospital



Routing Central Sterile Supply Department (CSSD)



CSSD: rinsing/washing

CSSD: washing/disinfecting

CSSD: sterilizing

Transport trolleys

Trolley/car washer

What to validate:

- Decontamination machines:
  - Washers
  - Disinfectors
  - Sterilizers
  - ...

Consider

- Procedures
- Documents
- People?

How to validate

- Items to use
  - Predetermined criteria
  - Efficacy/efficiency
  - Reproducibility

Schematic


Research Plan
Identification machine
Criteria to use
Who is performing
Who is responsible
Data acquisition
Observations
Documentation
Measurements
Tests
Report
Summary of research plan
Findings
Results
Conclusions

Criteria

- Prove your claim:
  - Claim: we use sterile medical devices in surgery
  - Prove that you use sterile medical devices on surgery
- Most easy way to prove that is to use norms and standards

Qualification

- Different kind of Qualifications
- All validations are Qualifications
- All definitions of Qualifications start with:

process of obtaining and documenting evidence

Design Qualification

process of obtaining and documenting evidence that equipment has been designed in accordance with its specification

Used during developing

Installation Qualification

process of obtaining and documenting *evidence* that equipment has been provided and installed in accordance with its specification

Could be used during installation or production.
Defined tests will be used

Operational Qualification

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

Used after installations with defined tests

Performance Qualification

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 product meeting its specification

Used before taking into the production process, loads of the hospitals will be used

Re-Qualification

repeat of part or all of the validation test requirements for the purpose of confirming process reliability

Used when the machine is in process, after maintenance or after a period of time (yearly)

When validation

Qualifications		Moment
– Design	→	During designing
– Installation	→	After manufacturing / installing
– Operational	→	Before using
– Performance	→	Before producing loads

Qualification in hospital setting

- New machine
  - IQ, OQ, PQ
- Machine in production
  - PQ: Major changes
  - PRQ: Periodical

What to “check”

- Technical layout
- Routine tests
  - Steam penetration test
  - Airleakage test
- Processes
  - Efficency/effficacy
  - Reproducibilty

Technical lay-out

- Mechanical parts:
  - Sealings
  - Indicators
  - Filters
  - Condition of pipework
  - Corrosion
  - Detergent pumps

Routine tests

- Penetration test
- Air leakage test

- Cleaning tests

Production processes

- Efficacy/efficiency
- Reproducibility

Example P(R)Q Steam sterilizer

- World wide most used sterilization method
- World wide most validated sterilizer
- Parametric validation

Step 1 -1: Research plan

- Identify sterilizer:
  - Hospital
  - Department
  - Sterilizer
- Criteria:
  - ISO17665 / EN285 (EN554)
- Kind of validation:
  - PQ (initial validation)

Step 1-2: Processes

- Sterilizer: number 1
- Processes Program 3: 134 °C – 3 min.
- Load Instruments and textiles
- Wrapping Non woven
- Loading Pattern Procedure 2007

Step 1-3: Measurement Program PQ

- Steam penetration (Bowie and Dick test)
- Air leakage test
- Program 3: 134 °C – 3 min. empty
- Program 3: 134 °C – 3 min. 50 % instruments
- Program 3: 134 °C – 3 min. 100 % instruments
- Program 3: 134 °C – 3 min. 50 % textiles
- Program 3: 134 °C – 3 min.100 % textiles
- Program 3: 134 °C – 3 min. 50 % mixed loads
- Program 3: 134 °C – 3 min. 100 % mixed loads

Step 1-3: Measurement Program PRQ

- Steam penetration (Bowie and Dick test)
- Air leakage test
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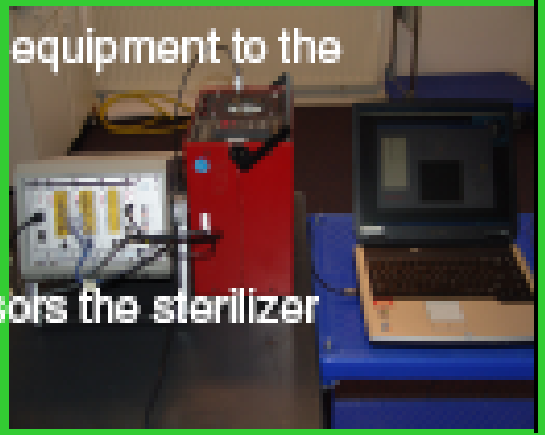
- Program 3: 134 °C – 3 min. 50 % textiles
- Program 3: 134 °C – 3 min.100 %textiles
- Program 3: 134 °C – 3 min. 50 % Mixed loads
- Program 3: 134 °C – 3 min. 100 % Mixed loads

Document Research plan

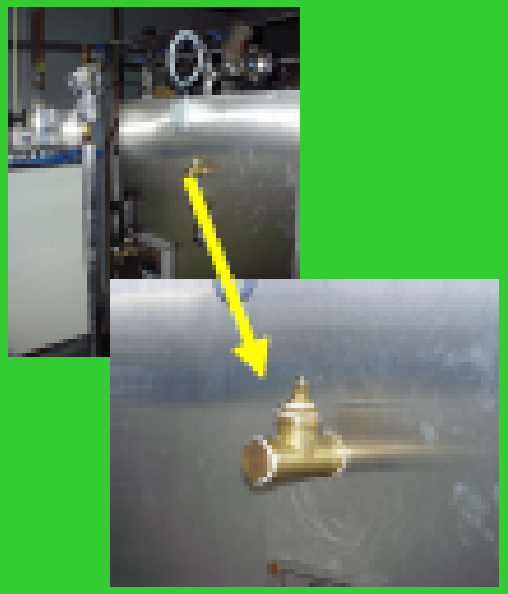
!!!Voorbeeld document Invoeren!!!

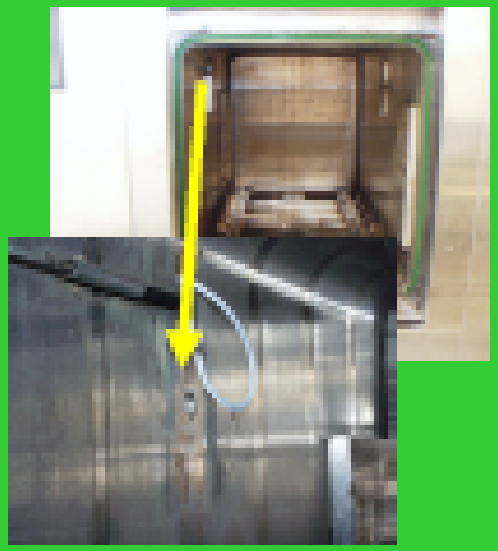
Step 2-1: arriving at the sterilizer

- Meet contact person / responsible person
- Discuss the research plan
- Bring the measurement equipment to the sterilizer
- Start calibration
- Start observations
- Start mounting the sensors the sterilizer



Step 2-2: connecting probes





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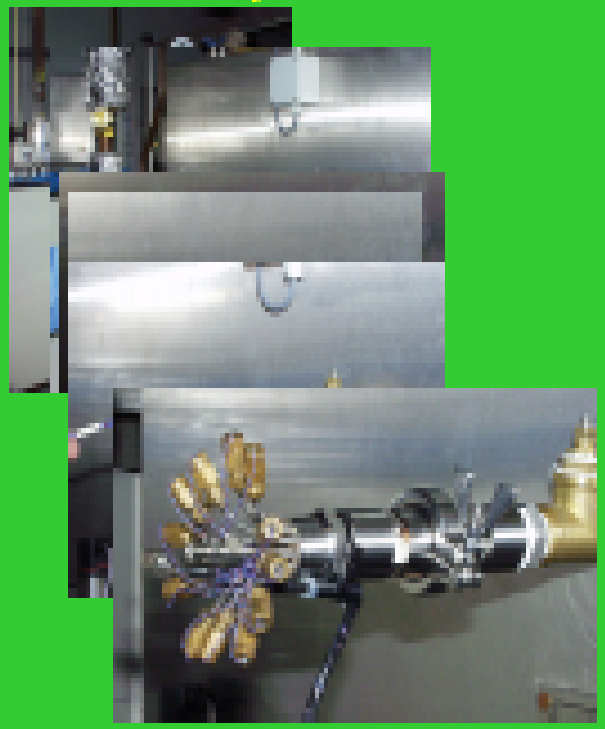
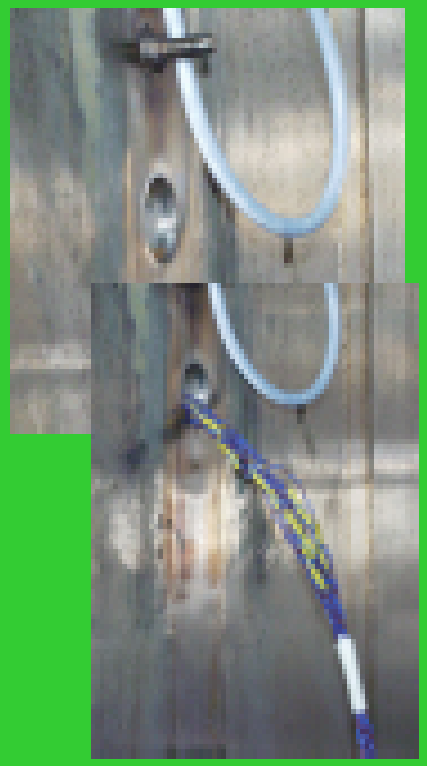
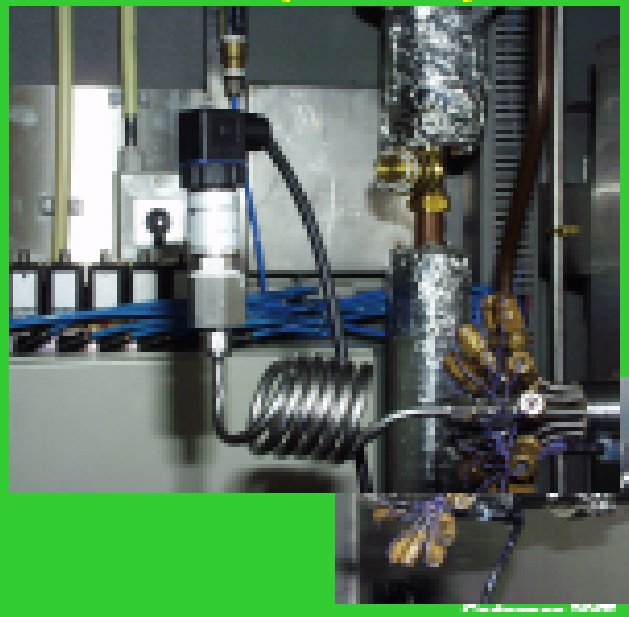
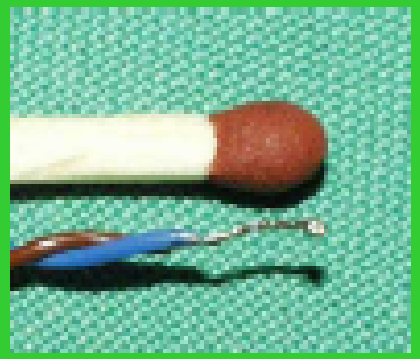




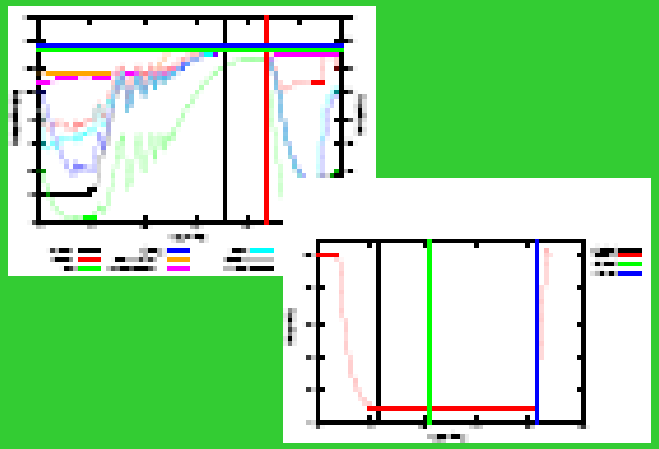
Step 2-2: probes / sensor



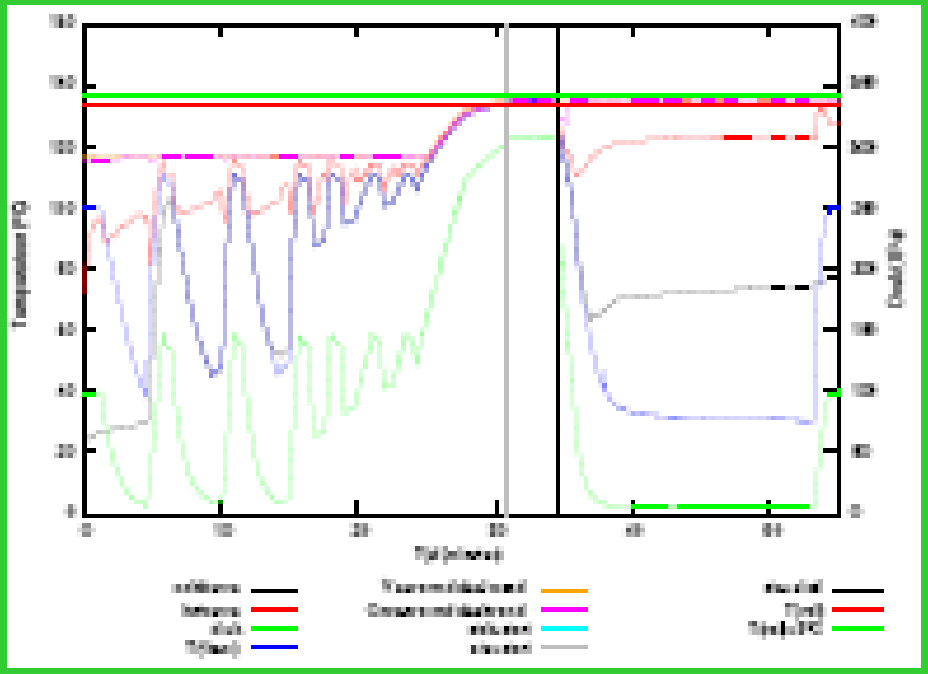


Step 2-3: Observation routine test

- Steam penetration test (B&D-test, helix, PCD)
- Air leakage test

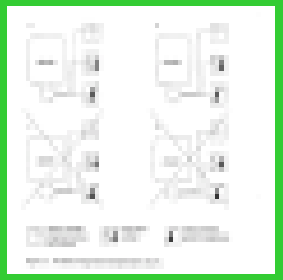


Step 2-4: Measurements



Step 2-5: Observation

Indicators



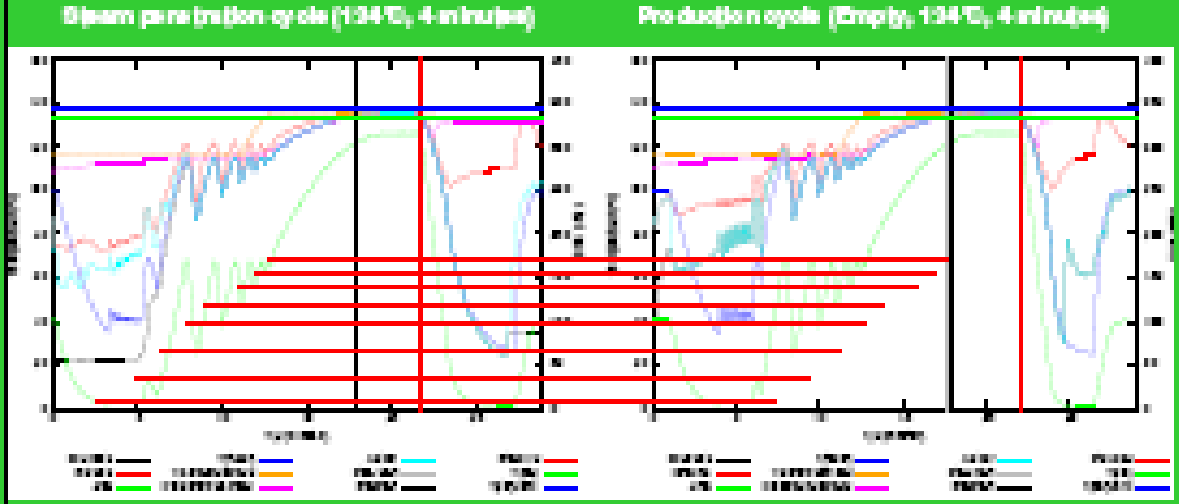
[Pictures: EN 60601]

Print outs

Step 3-1: reporting

- Contents report:
  - Summary
  - Research plan (N.B. Criteria!)
  - Calibration on side
  - Observations, measurements,…
  - Conclusions

Step 3-2: Efficiency and reproducibly



- Number of pulses, height and depth of the pulses must be identical
- Time of plateau period must be adjusted to used indicator material

Report contents

Summary of results

Report finished

- The report is send to the purchaser
- The report contains results but the cannot close a sterilizer

Report received by responsible person in hospital

- The result:
  - No derivations from predetermined criteria
  - Derivation from predetermined criteria
- The responsible person in the hospital takes (if necessary) appropriate measures

Necessity of validation

- Artikelen rapporten

Who may validate:

- Everybody

BUT

- Conflict of interest
- Knowledge
- Costs

Conflict of interest

- Hospital is validating
- Manufacturer/maintenance company
- Third party

Knowledge

- Criteria (literarture, norms and standards)
- Decontamination equipment
- Measurement equipment
- Calibration

Costs

- Time for:
  - Criteria (literarture, norms and standards)
  - Decontamination equipment
  - Measurement equipment
  - Calibration
- Investment in:
  - Education
  - Measurement equipment
  - Calibration

Conclusions

- Validation is the assurance:
  - safety of staff, patients, and environment
- Validation is an expertise
- Be careful with conflicts of interest

- Physical validation gives you insights, understanding and knowledge of your own process