PRACTICAL ISSUES - VALIDATION - STEAM STERILIZERS

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VDSMH; EXPERTS IN STERILE MEDICAL DEVICES
Thank you
• Most wanted British criminal was caught in Amsterdam

• Enquete from the RIVM to the Dutch hospitals regarding the validation of steam sterilizers
AVERAGE REACTIONS

VDSMH; EXPERTS IN STERILE MEDICAL DEVICES
FEBRUARI 28TH 2014

VDSMH; EXPERTS IN STERILE MEDICAL DEVICES
28 FEBRUARI 2014

Report

- 68 pages
- 4 empty pages -> 64 pages left to read
- 12 pages supplements -> 52 pages left to read

76.47%
STAKEHOLDERS

• Directors of the hospitals
• Experts in sterile medical devices
• Manager CSSD departments
• Manager operating theatres
• Validation companies
• Manufacturers of steam sterilizers
• Hospital Employees
• Patients
CONCLUSIONS

• Missing detailed Set of Recruitment for the validation
  - not clear what can be expected from the validation companies
  - not clear how to report the results of the validation
  - not clear how to interpret the results of the validation

• Shortcomings in the introduction of newly introduced medical devices in the hospital

• Not always using the correct and most recent, both national and international, standards

• Using no longer existing or outdated Standards

• Selection of the load to be validated

• Not making use of the results from the validation report approving the processes

• Not clear where the temperature sensors are located during the validation
APPLICABLE STANDARDS

Standard NEN-EN-ISO 17665-1

Describes what needs to be put in writing regarding:

- sterilizer
- sterilization process
- products that need to be sterilized

Guideline D6103 b (Very usefull Dutch ad-onn!!)

States demands for:

- performed measurements
- performed test
- required criteria
VALIDATION LOAD

• Various ways of loading the sterilizer
• Various ways of packaging medical devices
• Various products which resemble worst case load
• Adjusted (when applicable) in relation to the previous validation and newly bought reusable medical devices
• Load belongs to the sterilizationprogramm (121°C of 134°C)
ADVISE FOR THE RIVM

• Involve, while preparing the poll and the investigation, the professional associations
• Keep us alert and posted!!
ADVISE FOR MANUFACTURERS OF STEAM STERILIZERS

• Make sure that the specifications for the processes of the delivered steam sterilizer are
  - Describing the sterilization process and the relation with the typetest and the CE mark
  - Allowed tolerances
  - Specify the process parameters that can generate an error
  - Why the specifications are what they are
  - Based on specific loads
  - What can be sterilized and what can’t be sterilized in this steam sterilizer

• Send these specifications pro-active to the customers

• Better safe then sorry
ADVISE FOR THE VALIDATING COMPANIES  

1/2

• Take your responsibility!!
• Quality mark
• Take the role as an advisor because you are the expert!!
• Produce reports that are clear, easy to read and applicable to the standards
• Base your conclusions on the right data
• Take yourself serious and pay a lot of attention to the report (no copy/paste)
• Make sure your knowledge is up to date
  ◆ meet and use the right standards
  ◆ measurements performed meet the standards
  ◆ evaluate the results of the measurements in the correct way
ADVISE FOR THE VALIDATING COMPANIES

2/2

• Write your report clearly with a usable advise and discuss this with your customer

• Make sure your evaluation of the results is founded

• Make sure that the EXACT location of the temperature sensors are described in your report. (photos and numbers)
ADVISE FOR THE MANAGER OF THE CSSD DEPARTMENTS

• Take your responsibility!!
• Accept no new medical devices without the correct documentation
• Keep track of new medical devices for the next validation
• Make sure that you are involved in:
  - Drafting of the set of requirements
  - Determining the validation load
  - Discussing the results of the validation report
• Make sure your knowledge is up to date
• Make sure that there is a trend analysis from the daily processes of your steam sterilizers

VDSMH; EXPERTS IN STERILE MEDICAL DEVICES
ADVISE FOR THE EXPERTS IN STERILE MEDICAL DEVICES 1/3

- Take your responsibility!!
- Use the assessment criteria for reusable medical devices from the VDSMH as a tool to set up the medical device file of an instrument (ISO 17664)
- Make sure that in the purchasing process of new medical devices your decision is included in the actual purchase. Assessment by the expert in sterile medical devices MUST be a knock out criteria.
- Assess your own competences and, if necessary, make sure you get the right education to keep you up to date
- Decide which medical devices must be in the validation load, together with the manager of the CSSD department and your validation company
ADVISE FOR THE EXPERTS IN STERILE MEDICAL DEVICES 2/3

• Take the initiative to set up the requirements, together with the manager of the CSSD department and the validation company

• Assess together with these people if this set of requirements:
  ♦ complies to the standards
  ♦ will produce a clear output: understandable
  ♦ will produce a useful output: actions

• Know the steam quality in your hospital
  ♦ physical aspects (concentration NCG, overheating, dryness)
  ♦ chemical aspects

• Pay attention to the sterilization process of instruments with a lumen and with plastics, together with the producer of the steam sterilizer and instrument manufacturer
ADVISE FOR THE EXPERTS IN STERILE MEDICAL DEVICES

3/3

• Make sure you have a procedure to release your steam sterilizer which complies to the standards

• The RIVM advises to replace the empty chamber validation for a chamber validation with a minimum load. Together with the 50% and the 100% load tests this should be enough to check if your steam sterilizer complies to the standards. I think this opinion is open for discussion

• Take a close look to every part of the machine but don’t forget to also keep an eye on the system as one
TAKE HOME MESSAGE

• Know your competences and make sure that, if necessary, you will get the right and proper education

• Start a taskforce which
  • Clarifies the standards
  • Makes the standards usable and easy to be used
  • Create a step by step validation plan

• Use the competences of everyone involved: don’t do it all on your own!

"It's a pity you're not having an appendix operation - I'm rather good at that‼️"
Thank you for your attention.
Questions??