DSMH Vereniging van Deskundigen Steriele Medische Hulpmiddelen

PRACTICAL ISSUES – VALIDATION - STEAM STERILIZERS

H.W. OUSSOREN

VDSMH; EXPERTS IN STERILE MEDICAL DEVICES

Thank you

APRIL 5TH 2012

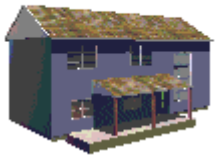
Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

of

Vragenlijst over de validatie van stoomsterilisatoren

- Most wanted British criminal was caught in Amsterdam
- **Enquette from the RIVM to the Dutch hospitals regarding the validation of steam sterilizers**

AVERAGE REACTIONS



FEBRUARI 28TH 2014

28 FEBRUARI 2014

Report

- 68 pages
- 4 empty pages -> 64 pages left to read
- 12 pages supplemants -> 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 Recruirement 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 interprate 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- **Using no longer existing or outdated Standards**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**

APLLICABLE STANDARDS

Standard NEN-EN-ISO 17665-1

Discribes 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 assocations**
- **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 sterlized 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 expertl!!**
- **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 trendanalysis from the daily processes of your steam sterilizers**

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 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 usefull output: actions**
- **Know the steam quality in your hospital**
  - **physical aspects (concentration NCG, overheating, dryness)**
  - **chemical apsects**
- **Pay attention to the sterilization process of instruments with a lumen and with plastics, together with the producer of the steam sterilizer and instument 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??