A study on introduction of SPSM for evaluating reliability of sterilization process
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Objective: By measuring 4 parameters of steam sterilization process (equilibration time, sterilization temperature band, holding time, and sterilization temperature uniformity) under daily condition, sterilization process safety margin was calculated to evaluate reliability and reproducibility of a steam process in a quantitative and feasible approach. A preventive maintenance in early stage through prospective risk analysis to avoid most of possible sterilization failures can now be performed.

Methods
1- P1 cycle of a sterilizer (Type MST-9615 HS2) currently in use was run with daily random loads and 4 key process parameters were measured. The results were evaluated against EN285.
2- Calculated safety margin. Currently there are no relevant definitions in international standards regarding the use of “safety margins” concept to evaluate sterilization process. Referring the calculation widely used in industry, we use the definition of “Sterilization Variable Safety Margin (SVSM)” and “Sterilization Process Safety Margin( SPSM)” as below:
SVSM%= ABS (Target Value –Measured value) / Target value .
SPSM%= Min (All specific 4 SVSMs).

Results:
1 SVSMs results (average and range): SVSM of equilibration time : 94.9% [86.7%-100.0%]; SVSM of sterilization temperature band: 67.3% [60.3%-71.0%]; SVSM of holding time: 72.0% [71.1%-72.8%]; SVSM of sterilization temperature uniformity: 83.1% [59.5%-93.0%]. Compliance of all 30 test runs to EN285 can be clearly confirmed.
2 SPSM result (average and range) : 66.8% [59.5%-71.0%]. (Results are shown in Figure 1).

3 Introduction of SPSM showed actual value of four parameters exceed 66.8% of required value on average. This SPSM as overall indicator can therefore be used to quantify the reliability of the sterilization process.

Conclusion:
1- The fundamental change in assessment of “quality” of sterilization process: CIs and BIs are non-quantitative methods and naturally cannot provide precise information. Introducing the concept of “safety margin” to quantify the reliability and reproducibility of sterilization processes in healthcare sector:
1.1 In this study, the average value of SPSM 66.8% was chosen as benchmark of SPSM for P1 program of this sterilizer. acting as an evaluation criterion of effectiveness of subsequent sterilization process tests. Whenever there is a situation in which SPSM of subsequent sterilization process is lower than the reference value, or SPSM of multiple tests fluctuate widely, it is a clear warning.
1.2- Generating a SPSM trend curve of a specific process based on the SPSM values calculated in every subsequent test can be realized, and be used for forward-looking risk analysis while gradually reducing the degree of dependence on CIs and BIs.