INADEQUATE PERFORMANCE SPECIFICATION CAUSES INCONSISTENT CHEMICAL INDICATORS RESULTS IN STEAM STERILIZATION CYCLES

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Introduction:
Chemical indicators (CI), especially type 5 and type 6, are designed to monitor the exposure time of a steam sterilization cycle, reacting to critical process variables to monitor steam sterilization, and in most institutions around the world, they are the key instrument used to clear sterilization loads for use. These indicators performance are steered by international standards, and challenged in a standardize equipment, known as Chemical Indicator Equipment Resistomer (CIER). Recent events have raised questions about the effectiveness of these indicators, especially when they are compared to the physical indicator (printout of the sterilizer), where both type 5 and type 6 reached the endpoint (approved) at the beginning of the exposure phase.

Objectives:
Determine the causes of the early approval results indicated by both CIs, type 5 and 6, validating the relation between chemical and physical indicators.

Methods:
Thermal qualification reports of 95 steam sterilizers, of 29 hospitals in Brazil, were analyzed to determine common come-up ramps, and to simulate them in a CIER vessel, a minimum observed come-up ramp of 3-minute, instead of the standardized 10 second. Triplicate studies were conducted in a CIER vessel, with both CIs, using first ISO 11140-1 test points, to demonstrate CIs endpoint performance, and after the same studies were performed with a 3-minute come-up ramp.

Results:
CIs endpoint performance were according to standardized specification on all cycles that were ran with the 10 second come-up ramp used to challenge this type of devices. When a 3-minute come-up curve is programmed, simulating actual hospital sterilizer, both indicators had their endpoint results out of standardized specification, with early approval results.

Discussion:
CIs are constructed according to ISO 11140 and have their efficiency tested in the CIER vessel, which only simulates the exposure phase of a sterilizer, not the real sterilization cycle. Also, thermal qualification standard, ISO 17665, does
not establish come-up ramp criteria, which allows qualified equipment to have come-up ramps ranging from 3 to 12 minutes. These evidences demonstrate that current cycle analysis based only on CI results are compromised and should not be used for approving a sterilization cycle. Cycle analysis must also use biological and physical indicator results before clearing the sterilized load.

Conclusion:
CIs endpoint performances are only obtained in CIER vessels. With a 3-minute come-up ramp, both CIs did not perform according to specification, but type 5 which is an integrator, can produce viable endpoint results at a maximum 3-minute come-up ramp. On the other hand, type 6 is not adequate in any come-up ramp duration, but the 10 second standardized configuration, and it should not be used at all. Both sterilization equipment and CI standards must be revised and include equal come-up ramp criteria. Due to these results, it is recommend, until standards are revised, that thermal qualification technicians limit come-up ramp to 3 minutes in their sterilization process qualification, allowing healthcare professionals to use type 5 CI, combined with biological and physical indicators results, assuring adequate cycle monitoring, observing local regulations and recommendations.