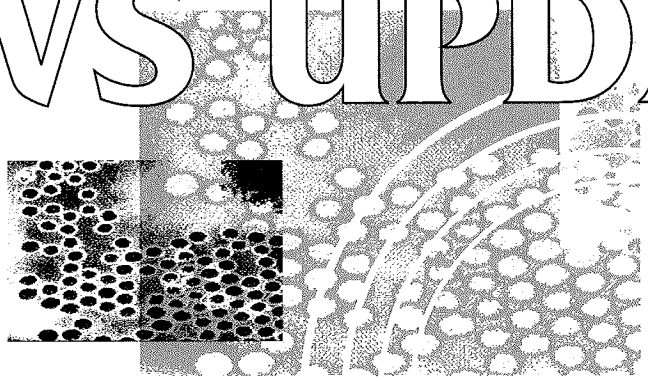
NEWS UPDATE



What's New in Standardisation

Determining the Process Challenge Location

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Chemical indicators can be used in the development and validation of a sterilization process as well as during routine operation and testing. EN ISO 15882 is a guideline for using the various chemical indicators as adapted to the updated standards of the EN ISO 11140 series. The draft of the new version of this guideline has now been published:

prEN ISO/DIS 15882:2007 Sterilization of health care products - Chemical indicators – Guidance for selection, use and interpretation of results

The standard presents indicators of Classes 1 through 6 as described in the standards of the EN ISO 11140 series. Class 6 indicators are not "better" than Class 1 indicators; rather, they serve different purposes.

These purposes are defined differently in different countries. The standard cannot resolve this conflict, but is forced to take the different perceptions into account. The standard is therefore unable to present a stringent and clear-cut picture; it should be read carefully while keeping in mind the technical background.

It would be a mistake to assume that chemical indicators are capable of demonstrating the presence of air or non-condensable gases. Chemical indicators do not react to air. As a general rule, indicator readings apply only to the location of the reacting substance during the process, e.g., the spot printed with indicator ink. Indicators show that certain preconditions required for successful sterilization were met in that location, for example the presence of moisture in steam sterilization.

prEN ISO 15882 defines the process challenge location (PCL) as the location where "the most unfavourable conditions" are present with regard to the sterilization medium. A process challenge location is not the absolute location with the most unfavourable conditions; rather it would have to be a location where an indicator can actually be placed.

Class 3, 4, 5 and 6 indicators are used in some countries as internal indicators within packs or trays and are intended to demonstrate that the conditions required for sterilization prevailed in that location. For textiles and instruments without gaps or lumens, the chance is fairly good for the location of an internal indicator to represent, if not exactly the place with the most unfavourable conditions, so at least a place where deficiencies may very well be present. However, this is far from achieving a sterility assurance level of 1,000,000 : 1. For this reason, the endpoint reaction of an indicator located in a suspected (difficult) area does not constitute proof that all products within the respective pack were actually sterilized.

In the case of complex instruments with various types of gaps and lumens, determining the location where the most unfavourable conditions prevail requires tremendous effort, and the exact location will, for most practical purposes, have to be considered as unknown. Not infrequently, areas with conditions unfavourable to sterilization – due to the presence of areas impermeable to steam or of lubricants and condensate – will be very small, and the areas most difficult to sterilize will often also be the areas that are most difficult to access or completely inaccessible. Indicators cannot be placed in these locations during routine operations.

prEN ISO 15882 is completely justified in asserting that the reaction of an indicator placed next to such instruments cannot be interpreted as confirmation that the instruments were sterilized successfully. The performance of a validated procedure for sterilization of instruments with gaps or lumens can therefore not be confirmed using internal indicators; this requires the use of process challenge devices (PCD).

A process challenge device is a combination of a test specimen and a measuring device or indicator system. A PCD may either be part of the sterilizer or part of the load.

The truly most unfavourable location within the load is never known. The assumption that a process challenge device represents the most unfavourable conditions within a given load, however, could only be verified by comparing the conditions at the location of the PCD with the conditions in the most unfavourable location. Since this is not possible, the underlying assumption is inadmissible. The proposal in prEN ISO 15882 to use many indicators or PCDs instead of a single indicator is based on this inadmissible as-

sumption and therefore does not constitute a valid solution to the problem.

The purpose of a process challenge device is not to represent the load but to challenge the process. The reaction of the process challenge device depends on the design of the sterilizer, the sterilization cycle, the type of problem encountered, the type and structure of the load and the location and orientation of the PCD within the load. Sterilizer, cycle, process challenge device and process challenge location should always be determined prior to evaluating the PCD and PCL in order to minimize the number of necessary tests.

If this condition is met, the performance of a PCD positioned in a specific way can be confirmed when processing reference loads. Still, this confirmation requires at least 30 testing cycles for each sterilizer type, under conditions of inadequate air removal, leaks and non-condensable gases within the steam. EN ISO 17665-1 assumes that the sterilizer manufacturer performs these tests and defines the correct process challenge location and process challenge device. ✦