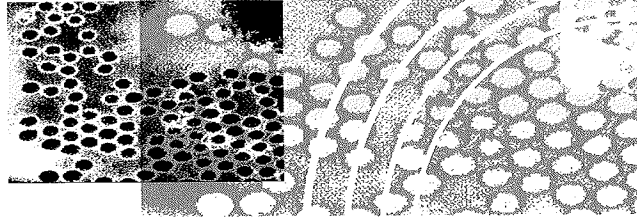


# NEWS UPDATE



## What's New in Standardisation

# Biological Indicators

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The revised standard EN ISO 11138 was adopted when put to the final vote; it supersedes EN 866 regulating biological systems for testing sterilizers. These standards are directed at the manufacturers of biological indicators. EN ISO 14161 serves as a guide to selection and use of biological indicators as well as to the interpretation of results; revision of this standard has just begun.

A biological indicator is defined as "a test system containing viable microorganisms providing a defined resistance to a specified sterilization process". A biological indicator need not be ready for use, as still specified in EN 866. An inoculated carrier without packaging can be designated and used as a biological indicator. Likewise, the surgical instrument inoculated under laboratory conditions for testing with a spore suspension is a biological indicator. This change can be confusing for readers who had become accustomed to the old definition.

EN ISO 11138 *Sterilization of health care products – Biological indicators* comprises the following parts:

- Part 1: *General requirements*
- Part 2: *Biological indicators for ethylene oxide sterilization processes*
- Part 3: *Biological indicators for moist heat sterilization processes*
- Part 4: *Biological indicators for dry heat sterilization processes*
- Part 5: *Biological indicators for low-temperature steam and formaldehyde sterilization processes*

In the case of gas sterilization, biological indicators must be used at least for process definition and validation. Moreover, biological indicators are needed for development and definition of medical devices as well as for development of process challenge devices intended to be representative of individual devices or product families, even if the manufacturer specifies steam sterilization in his user instructions.

But this should not be misunderstood. These tests are carried out in the laboratory at a sterilization temperature of 121 °C. For definition of a process with moist heat as per the "overkill method", EN ISO 17665-1 stipulates that special biological indicators with a resistance of more than 12 minutes at 121 °C be used. In the healthcare sector, predominantly processes with a sterilization temperature of 134 °C and holding time of at least 3 minutes are used. The microbial reduction achieved in such a process is around 1,000,000 times greater than for the processes defined as per the "overkill method". Conventional biological indicators cannot demonstrate this safety for steam sterilization at 134 °C. But since this level of safety is required, biological indicators are not recommended for testing such processes.

Parts 7 and 8 of EN 866 with requirements for self contained biological indicators for use in steam sterilizers or in ethylene oxide sterilizers are being withdrawn. These units contain, in addition to the carrier, a nutrient medium for culture.

Such indicators are used primarily for routine tests.

EN 866 Part 4 regulating systems for use in radiation sterilizers is being likewise withdrawn because EN ISO 11137 – Requirements for the development, validation and routine control of a radiation sterilization process stipulates: "The use of biological indicators for validation and process monitoring is not recommended for radiation sterilization because the relationship between the microbicidal action and radiation dose is well established." The radiation dose is checked with dosimeters. ♦

## Erratum

In Issue 3/2006 of Central Service p. 189 the publication "28th National Sterilisation Days (in the Healthcare Services), 12–13 April 2006, Tours, France" one of the CEFH prizewinners was incorrectly named as Dominique Gambaud. This passage should have stated the following: "Then the CEFH prizes were awarded, for sterilisation (Dominique COMBEAU, Paris), quality in care (Olivier Meunier, Sarrguemines) and hygiene /infection control (Françoise Ulmann, Aix-en-Provence)".

We apologise for this oversight. ♦