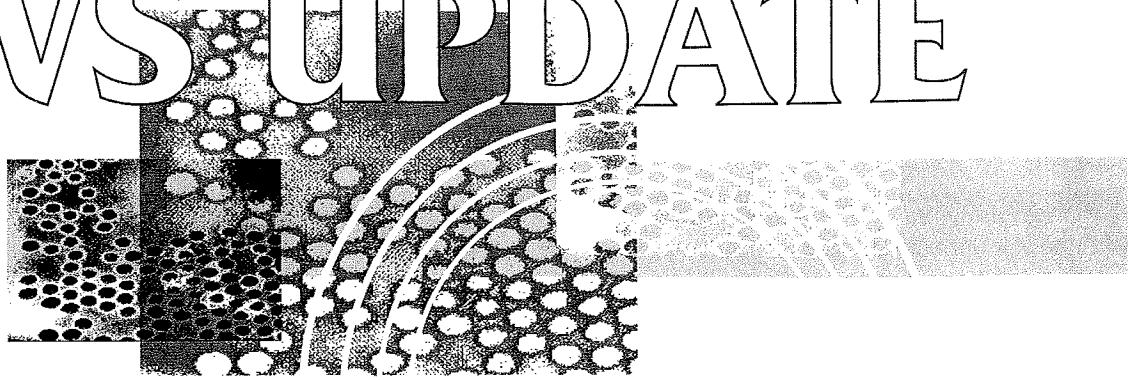
NEWS UPDATE



What's New in Standardisation

EN ISO 17665 to supersede EN 554

Ernst Dennhöfer, Cologne

The final version of EN ISO 17665-1 was adopted with a vast majority of votes. Experts from America, Asia, Australia and Europe had taken part in compilation of this standard.

EN ISO 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

EN ISO 17665 is the basic standard for sterilization with moist heat; it describes the current state of the art and is to replace the standards EN 554, ISO 11134 and ISO 13683 over a 30-month transition period. National standards regulating steam sterilization in the healthcare setting, e.g. DIN 58946-6, will also become invalid.

EN ISO 17665 is valid for sterilization of solid (massive, hollow or porous) as well as liquid medical devices (e.g. irrigation solutions that are heated up indirectly in glass bottles) in the industrial and healthcare settings, regardless of the sterilizer chamber size. EN ISO 17665 is thus also valid for sterilization with small steam sterilizers in the field of dentistry.

This standard presupposes that the reader has extensive expert knowledge, since the requirements are only cursorily listed without any further explanation. Gaining an understanding of this standard is made even more difficult for the reader because of the multitude of new technical terms used and because of the structure of the standard, which is based on the principle of the development lifecycle.

The manufacturer must develop the process for the entire lifecycle, specifying instructions for routine operation and must also state how the equipment and process are to be tested.

EN ISO 17665 calls for a detailed description of all conditions affecting or designating (process variables) the process performance. Examples of this are the pressure-change points, the speed at which each pressure change occurs and the concentration of non-condensable gases in the steam. If these conditions are subject to variation, e.g. as a function of the different loads processed in the sterilizer, verifiable values (process parameters) and tolerances must be specified for them. While the standard acknowledges the implications that these influence factors can have for the effectiveness of the process, it does not stipulate any limit values or tolerances, not even for the sterility assurance level (SAL), for safeguarding the sterile supplies until the time of use, for steam penetration of the load or for the reproducibility of the process. It was not possible to achieve worldwide standardization of these values.

All requirements must be met before commencement of routine operation and must be confirmed at the time of validation; physical tests are stipulated. But the standard does not specify how, by whom and in what order the tests are to be conducted.

The standard gives the expert tremendous discretionary powers. Informative Guide ISO/TS 17665-2 is to feature explanations, examples and a description of appropriate methods for uniform interpretation and implementation of ISO 17665-1. It is expected that this guide will be put to a vote already during the summer of 2006. In Europe implementation of EN ISO 17665 will be facilitated by the fact that there already exists an impressive library of harmonized standards, including EN 556-1 regulating the property "sterile", EN 285 and EN 13060 for steam sterilizers, EN ISO 17664 for processing of medical devices, EN ISO 11607 and EN 868 for sterile packaging as well as EN ISO 11138 and EN ISO 11140 together with EN ISO 14161 and EN ISO 15882 regulating the use of biological and chemical indicators, in addition to referenced standards including EN 61010-2-040 regulating the operating safety of sterilizers.

EN ISO 17665 cannot be implemented directly in the CSSD. Based on the manufacturer's instructions and the test results, the CSSD management must conduct risk and hazard analyses and compile standard operating procedures (SOPs). In a large CSSD this task can take several months to accomplish, or can even prove an impossible feat if the developer of the sterilization process does not prove to be sufficiently cooperative. ✦