SLOVENSKI STANDARD
SIST CR 14252:2002

01-maj-2002

Uskladitev mikrobioloških standardov – Seznam delovnih osnutkov standardov splošnega pomena

Co-ordination on microbiological Standards - Register of work items of common interest

Ta slovenski standard je istoveten z: **CR 14252:2001**

ICS:

01.120	Standardizacija. Splošna pravila	Standardization. General rules
07.100.01	Mikrobiologija na splošno	Microbiology in general

SIST CR 14252:2002 **en**

CEN REPORT

RAPPORT CEN

CEN BERICHT

CR 14252

August 2001

ICS

English version

Co-ordination on microbiological Standards - Register of work items of common interest

This CEN Report was approved by CEN on 16 June 2001. It has been drawn up by the Technical Committee CEN/CS SUBSECTOR S99.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. CR 14252:2001 E

Scope

This CEN Report is designed to give a view of CEN Standards activity containing microbiological aspects. It takes the form of a register of work items. The register includes current work items and published Standards from TCs which are working on standards containing microbiological aspects. The information in this register was produced on February 2001.

The intended audience of this Report is those people working in Standardization who have an interest in microbiological aspects. It will be particularly useful for those people working on a subject with microbiological aspects, who wish to co-ordinate their efforts and therefore avoid duplication of work. In particular, this report is intended to assist in the evolution of common terms and definitions in standards that involve microbiological aspects.

The register is not exhaustive. There may be other CEN TCs with microbiological aspects but these are not known at the time of writing this CEN Report.

Not all the information is available for all the work items listed.

Additional notes to the table

The degree to which each of the work items and standards listed includes microbiological aspects will vary. Individual drafts and published Standards should be consulted if a title listed below indicates that the work may be of interest.

CEN/TC 216 Chemical disinfectants and antiseptics: By the nature of the subject covered by CEN/TC 216 all of its work items (present and future) can be considered to have microbiological aspects.

Further research is recommended for people needing complete and more detailed information on microbiological activity in Standardization.

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
102002	Sterilization – Steam sterilizers – Large sterilizers (EN 285:1996)	CEN/TCs 233 216 204		Requirements and methods of test for large steam sterilizers primarily used in healthcare for sterilization of one or more sterilization modules for wrapped goods (instruments etc. and porous loads). Can also be used during commercial production of medical devices. Not applicable to small steam sterilizers or those used for sterilizing pharmaceutical products.	Relationship with WI 233 079 – Performance criteria for steam sterilizers and autoclaves (EN 12347). Relationship with WI 00204027 and 00204009 validation and routine control of moist heat sterilization (process). These work items are related to EN 554 CEN/TC 216 corrected the definition of 'moist heat sterilization conditions' and conformed it to EN 554 (CEN/TC 204). EN 285 is now currently under revision (see WI 102048). mandated (BC/CEN/93/8.8).
102010	Sterilizers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods (EN 1422:1997)	CEN/TC 204		Requirements and test methods for ethylene oxide sterilizers used for medical, dental pharma-ceutical, veterinary and industrial or related purposes.	Related to WI 204025 and 204005. These are related to EN 550. Mandated (BC/CEN/93/8.13).
102026	Sterilizers for medical devices – Steam sterilizers – small sterilizers- Requirements and testing	CEN/TCs 233 204		Specifies requirements and test methods for small steam sterilizers that are used primarily for the sterilization of medical devices. Not for use for liquids or pharmaceutical products.	Possible relationship with WI 233 079 and 204005. These are related to EN 550. Relationship with WI 00204027 validation and routine control of moist heat sterilization. Mandated (BC/CEN/93.8.12).

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
102005	Packaging materials and systems for medical devices which are to be sterilized – Part 1 : General requirements and test methods (EN 868-1:1997)		ISO/TC 198	General requirements for single use and reusable materials for packaging of terminally-sterilized medical devices. Test methods for microbial barrier properties are included in an informative annex.	Some common objective with CEN/TC 243 work but no overlap. Related to ISO 11607. Start of harmonization of ISO 11607 and EN 868 under discussion. Material specific requirements and test methods are included in EN 868 part 2 to 10 (WI 00102013 to 00102019; WI 102028 and WI 00102029). Mandated (BC/CEN/89/9.9).
   102020 102021 102022 102031 102032	Biological systems for testing sterilizers and sterilization processes (EN 866 series) Part 1: General requirements Part 2: Systems for use in ethylene oxide sterilizers Part 3: Systems for use in steam sterilizers Part 4: Systems for use in irradiation sterilizers Part 5: Systems for use in low temperature steam and formaldehyde sterilizers	CEN/TCs 233 204	ISO/TC 198	All parts specify requirements for inocculated carriers and bio-logical indicators intended for use in assessing the performance of different types of sterilizers. Suitable test organisms, e.g. spores of Bacillus subtilis var.niger (Part 2), Bacillus stearothermophilus (Part 3), are tested in an apparatus (resistometer) simulating typical sterilization process and decimal reduction values (D values) determined by the survivor curve and most probable number (MPN) methods. Specifies recovery conditions.	Related to ISO 11138 Parts 1 to 3; harmonization of EN 866 and ISO 11138 series is in progress (see WI 102050 to 102057); deletion of WI 102053 - biological indicators for radiation sterilization - is under consideration; related to 204025 to 204027 - harmonization of EN 550/ISO 11135; EN 552/ISO 11137; EN 554/ISO 11134/ISO 13683 dealing with validation and routine control of ethylene oxide sterilization, irradiation sterilization and moist heat sterilization respectively, i. e. as process and related to EN ISO 14937 dealing with general requirements for characterization of a sterilizing agent

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102033	Part 6: Systems for use in dry heat sterilizers				and the development, validation and routine control of a sterilization process for medical devices.
102034	Part 7: Self-contained biological indicator systems for use in steam sterilizers				EN 866 Parts 1 to 3 mandated BC/CEN/89/9
102035	Part 8: Self-contained biological indicator systems for use in ethylene oxide sterilizers				Terminology of culture medium etc... Terminology of culture medium would have an impact on this work. Relationship with preservation of organisms.
	Non-biological systems for use in sterilizers (EN 867 series)	CEN/TCs 233 204	ISO/TC 198	Requirements for various types of chemical indicators used to monitor the presence of attainment of one or more of the variables required for a satis-factory sterilization process. No biological systems are involved. Chemical indicators are classified into: - process indicators (class A) - indicators for use in specific tests (class B) - single-variable indicators (class C) - multi-variable indicators (class D) - integrating indicators (class E) Guidance for the selection and use of biological indicators and for the interpretation of results when used in development, validation and	All parts are published exept part 5 which is at formal vote. - related to ISO 11140 series; harmonization of EN 867 and ISO 11140 series proposed by CEN/TC 102 and accepted by ISO/TC 198 (Vienna Agreement, ISO lead) awaiting target dates and work item proposals from ISO/TC 198/WG 6. - related to 204025 to 204027 - harmonization of EN 550/ISO 11135; EN 552/ISO 11137; EN 554/ISO 11134/ISO 13683 dealing with validation and routine control of ethylene oxide sterilization, irradiation sterilization and moist heat sterilization respectively, i. e. as process and related to EN ISO 14937 dealing with general requirements for
102023	Part 1: General requirements				
102024	Part 2: Process indicators (class A)				
102025	Part 3: Specification for class B indicators for use in the Bowie and Dick test				
102036	Part 4: Performance specification and test methods for indicators as an alternative for the Bowie and Dick test for the detection of steam penetration				
102037	Part 5: Specification for indicator systems and processes challenge devices for use in performance testing for small sterilizators class				

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				routine monitoring of sterilization processes. Assists users in the application of biological indicators for existing and new processes which are not addressed by existing standards.	characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. EN 867 parts 1 to 4 :prEN 867 part 5 Mandated BC/CEN/93/8.14 BC/CEN/93/8.15 BC/CEN/93/8.16 BC/CEN/95/33.1 BC/CEN/95/33.2
102045	Sterilziation of health care products – Biological indicators – Guidance for the selection, use and interpretation of results (EN ISO 14161:2000)		ISO/TC 198		
102049	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results (ISO/DIS 15882:2000)		ISO/TC 198	Provides guidance for the selection, use and interpretation of results of chemical indicators used in process definition, validation, and routine monitoring and control of sterilization processes. This document applies to chemical indicators for which International Standards exist. (See ISO 11140 series).	
102038	Washer disinfectors (prEN ISO 15883 Parts 1 to 4) Part 1: General requirements,	CEN/TCs 216 233	ISO/TC 198	Specifies performance requirements for washer-disinfectors and their accessories that are intended to be used for cleaning and disinfection of	Mandated (BC/CEN/95/33.3)

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
	definitions and tests	Possible relationship		re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as the accessories which may be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified. laundry and general catering purposes are excluded	
102039	Part 2: Requirements and tests for washer disinfectors for surgical instruments and trays, anaesthetic equipment, holloware and glassware.				(BC/CEN/95/33.4.2)
102040	Part 3: Requirements and tests for washer disinfectors for human waste containers				(BC/CEN/95/33.5.2)
102043	Future part 4: Requirements and tests for washer disinfectors for thermolabile instruments including endoscopes				
102046	Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and test methods"			Specifies minimum performance requirements and test methods for sterilizers using a mixture of low temperature steam and formaldehyde as sterilizing agent. These sterilizers are primarily used for sterilization of heat labile medical devices in health care facilities.	Relation to EN ISO 14937 dealing with general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices; new work item proposal of CEN/TC 102/WG 6 on validation and routine control of a low temperature steam sterilization process under consideration (this new work item proposal will be submitted CEN/TC 204 after discussion within CEN/TC 102)

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
Possible addtion to the work programme of CEN/TC 102	Sterilization of health care products - Biological indicators - Method for validation of biological indicators growth period (ISO/TS 16342)		Work going on in ISO/TC 198	Includes information and methods used to validate biological incubation period	
140 014	In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (EN 12376:1999)		ISO/TC 212		Published standard Relationship with ISO/DIS 19001
140 024	In vitro diagnostic systems - Culture media for microbilogy - Terms and definitions (EN 1659:1996)	TC 216 TC 230 TC 275 TC 302		Applies to culture media for microbiological purposes and defines terms associated with culture media. Definitions include those of the following terms: culture medium, chemically defined culture medium, chemically incompletely defined culture medium, liquid culture medium, solid and semi-solid culture media, transport medium, preservation medium, resuscitation medium, enrichment medium, non-selective enrichment medium, isolation medium, selective isolation medium, non-selective isolation medium, differentiation medium, dry medium, partially complete medium, ready-to-use medium	Published standard Possible relationship with work items concerning culture media in several TCs (e.g. TC 216, TC 230, TC 275). Some related work in ISO/TC 34/SC9. Possible relationship with ISO/TC 212.

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
140031	In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media (EN 12322:1999)	TC 216 TC 230 TC 275 TC 204 TC 243	ISOTC 34/SC9		Published standard Possible relationship with work items concerning culture media in several TCs (e.g. TC 216, TC 230, TC 275). Possible relationship with ISO/TC 212.
153 (various)	Food processing machinery Example: EN 1672-2 Food processing machinery – Basic concepts – Part 2: Hygiene requirements“	TC 233 TC 205 TC 216		TC 153 deals with „Food processing machinery“, most of which are open, batch-operated machines, used in small shops (bakeries, butcheries, catering companies, retaurants, etc.) and also in food industry. There are several Working Groups e.g. WG 1 „Bakery Machinery“, WG 4 „Catering equipment“ a.s.o. We elaborated a „basic“ harmonized European Standard, which shall be valid for all machinery dealt with in TC 153.	The aim of the TC 153 – work is to give assistance to the manufacturer and to the officials to meet the essential hygiene requirements of the Machinery Directive Annex, 1.2 „Food processing machinery“ by elaborating appropriate clauses. In addition to this, the Working Groups elaborated an Annex to the product (C-) standards, called „Principles of design to ensure the cleanability of.... (name of type of machine)“. This annex is nearly identical for all standards of CEN/TC 153 and gives additional and more detailed specifications than EN 1672-2.
170048	Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy of multi-dose preserved contact lens care products (EN ISO 14730:2000)	CEN/TC 216	Work done in ISO/TC 172/SC 7		Published standard
170049	Ophthalmic optics – Contact lens care products –microbiological requirements and test methods for products and regimes for hygenic management of contact lenses (prEN ISO 14729)	CEN/TC 216	Work done in ISO/TC 172/SC7		Project at Formal Vote

WI No	Title	Related work in	Related ISO	Scope of WI / principle involved	Comments
204005	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization EN 550:1994	TC 102	ISO/TC 198	Specifies requirements for the development, validation, process control and monitoring of the sterilization of medical devices using ethylene oxide. Includes requirements for microbiological performance qualification using either survivor curve or fraction-negative method.	Related to ISO 11135. Mandated (BC/CEN89/9.13)
204007	Sterilization of medical devices - Validation and routine control of sterilization by irradiation EN 552:1994	TC 102	ISO/TC 198	Specifies requirements for the validation, process control and monitoring of the radiation sterilization of medical devices using 60 Co or 137 Cs, or electrons at or below an energy level of 10 MeV.	Related to ISO 11137. Mandated (BC/CEN/89/9.15)
204009	Sterilization of medical devices - Validation and routine control of sterilization by moist heat EN 554:1994	TC 102 TC 233	ISO/TC 198	Specifies requirements for the process development, validation, process control and monitoring of the sterilization of medical devices using moist heat.	Related to ISO 11134. Mandated (BC/CEN/89/9.17)
204011	Sterilization of medical devices - Requirements for medical devices to be labelled "sterile" EN 556:1994	TC 102 TC 233 TC 316 TC 140 TC 170	—	Specifies requirements for a terminally-sterilized medical device to be labelled "STERILE". Not applicable to IVDs.	Of possible interest to other sectors, especially definitions of "bioburden", "sterility" and "sterile". Mandated (BC/CEN/89/9.19)
204012	Sterilization of medical devives - Estimation of the population of micro-organisms on product - Part 1: Requirements EN 1174-1:1996	TC 243 TC 216 TC 233 TC 205	ISO/TC 198 ISO/TC 209	Specifies general criteria to be applied in the estimation of the population of viable micro-organisms on a medical device or on a component, raw material or package. This estimation consists of both identification and enumeration of the population. Does not apply to viruses. Further more detailed information is given in Parts 2, 3 and 4.	Related to ISO 11737-1. Mandated (BC/CEN/89/9.36)