Liaison report to CEN TC 55 Bratislava March 2009

Reported by T E Prodger

CEN TC 204 STATUS OF ACTIVE WORK

CEN WI/ BSI Ref	EN No	TITLE	ROUTE	STAGE		WAITING FOR
				CURRENT	NEXT	
039	prEN ISO TS 11135-2	Sterilization of health care products - Ethylene oxide --Part 2: Guidance on the application of EN ISO 11135-1	Ratified			
040	prEN ISO TS 17665-2	Sterilization of healthcare products -- Moist heat --Part 2: Guidance on the application of EN ISO 17665-1	Ratified			
041	prEN ISO 14937 rev	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	VA/ISO		Registered for FDIS 29 Jan 2009	ISO/CS to issue FDIS
043	prEN ISO 11737-2 rev	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process (ISO 11737-2:1998)	VA/ISO	Close of Enquiry 06 May 2008	Registered for FDIS 29 Jan 2009	ISO/CS to issue FDIS
042	prEN ISO 14160 rev	Sterilization of single-use medical devices incorporating materials of animal origin - validation and routine control of a liquid chemical sterilant	VA/ISO	CD registered 20 January 2009	CD issue	ISO/TC198 to issue CD
041	prEN ISO 14937 rev	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validationand routine control of a sterilization process for medical devices	VA/ISO	Close of Enquiry 23 April 2008	Registered for FDIS 29 January 2009	ISO/CS to issue FDIS

CEN TC55 STATUS OF ACTIVE WORK (cont)

CEN WI/ BSI Ref	EN No	TITLE	ROUTE	STAGE		WAITING FOR
				CURRENT	NEXT	
045	prEN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	VA/ISO	Close of Enquiry 08 May 2008	Registered for FDIS 29 January 2009	ISO/CS to issue FDIS
00204C05	EN ISO 11137-2:2007/prAC	Sterilization of health care products - Radiation sterilization dose (ISO 11137-2: 2006, corrected version 2006-08-01)	CEN	Corrigendum registered 12 January 2009		
00204C06	CEN ISO/TS11135 - 2:2008/prAC	Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO11135-1 (ISO/TS 11135 - 2:2008)	CEN	Corrigendum registered 12 January 2009		
xx	EN ISO 11135 -1:2007	Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 11135-1:2007)	Corrected and reprinted E & F ISO stds published 01/11/2007		CMC to adopt corrected versions	No project registered In CEN or ISO/TC198

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ACTIVE WORK ITEMS IN ISO TC 198 RELEVANT TO CEN TC 204

CEN TC 204 listed items

ISO/PRF TS 17665-2 *Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1.*
Although the document was approved, dissatisfaction with the document from some National Bodies was voiced. It will be published after revision by the ISO editors. The significant technical comments have been deferred for the first revision. These relate to reservations on the methods proposed and whether or not the document is of real value in implementing Part 1. (CEN ref 040) NOTE: Work to be started on product families classification, as referred to in the Performance Qualification section and then on a new steriliser standard for moist heat applications.

ISO/DIS 11737-2 *Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*
Approved but there were a lot of technical comments including some from the CEN consultant. These were resolved by discussion at the last meeting and a FDIS is being prepared.
(CEN ref 043)

ISO/DIS 14937 Sterilization of health care products -- *General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process.*
Approved to proceed to a FDIS.
(CEN ref 041)

ISO/CD 11137-2 *Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.*
With 200 comments received there has been a substantial rewrite but the WG has agreed to issue the next text as a DIS.
(CEN ref 00204C06)
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SO/NP TS 13004 - *Expansion of VDmax substantiation doses in ISO 11137-2.*
This will extend the range of doses that can be selected for VDmax substantiation.
(CEN ref 00204C06)

ISO/CD 14160 *Sterilization of single-use medical devices incorporating materials of animal origin -- Validation and routine control of sterilization by liquid chemical sterilants.*
Approved for issue as a DIS.
(CEN ref 042)

Relevant items not listed on CEN TC 204 active list

ISO/DIS 14161 *Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results.*
Approved to proceed to a FDIS.

ISO/DIS 20857 *Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of an industrial sterilization process for medical devices.*
Text approved and it will proceed to a second enquiry.

ISO/DIS 25424 *Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices.*
Approved to proceed to a FDIS.

ISO/CD 11140-6 *Sterilization of health care products – Chemical indicators – Part 6: Class 2 indicators and process challenge devices for use in performance testing for small steam sterilizers.*
As there were over 300 comments this has been redrafted and will be issued as a second CD rather than a DIS although the problem areas have been resolved.

ISO/CD 15883-6 *Washer-disinfectors – Part 6: Requirements and tests for general purpose washer-disinfector employing thermal disinfection.*
Revised text is being advanced for parallel ISO and CEN enquiry ballots.

New Work Item Proposals approved

ISO/NP 13408-7 *Aseptic processing of health care products -- Part 7: Aseptic qualification of solid medical devices and combination medical devices.*

New ISO Standard, ISO 13408-8 *Aseptic processing of health care products – Part 8: Cell-based health care products.*

ISO/NP 11138-6 - *Sterilization of health care products -- Biological Indicators – Part 6: Biological indicators for hydrogen peroxide vapour sterilization processes.*

T E Prodger

For CEN TC55 meeting Bratislava March 2009