Standards: Overview and Up-date

Quality Assurance in CSSD by Compliance to Standards

Klaus Hahnen, 3M, Germany

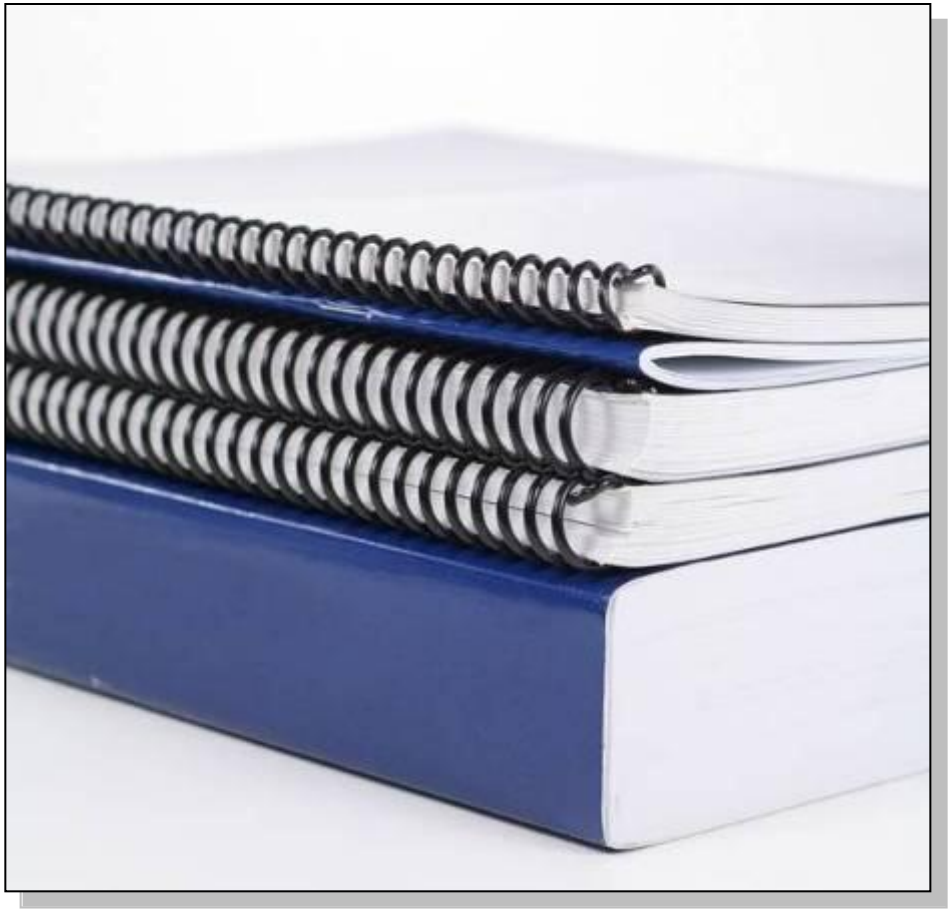
Note: all information dated November 2011!

Purpose of the Presentation

- Provide a brief introduction to standards, standardization bodies and how standards are generated
- Introduce the current sterilization and associated standards including:
  - *the quality/terminology standards*
  - *the processing standards*
  - *the product standards*
- Details from some key standards (i.e. for moist heat)

Note: all information dated November 2011!

Standards – Background



Note: all information dated November 2011!

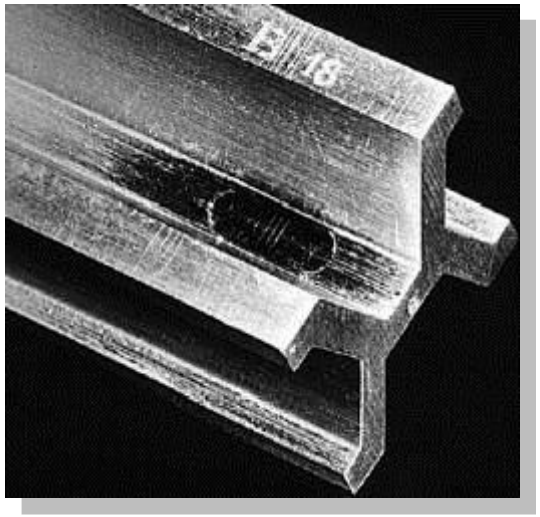
What are standards?

- Standards are:
  - *written documents*
  - *agreed by consensus of all parties involved*
  - *approved by a recognized regulating body*
  - *a specification for a given device or a process designed to achieve a desired end point*

Note: all information dated November 2011!

The Meter – the modern standard of length

- defined by the French Academy of Sciences as the length between two marks on a platinum-iridium bar
- representing one ten-millionth of the distance from the Equator to the North Pole along the Paris Meridian.
- In 1983, the metre was redefined as the distance travelled by light in free space in 1⁄299,792,458 of a second.



Note: all information dated November 2011!

Why do we need them?

- To ensure that what we want is what we get
  - *e.g. purchasing specification*
- To avoid cross border barriers to trade
- To enable a universal approach to achieving a given objective
  - *e.g. a sterile product*

Note: all information dated November 2011!

Standardisation of Outcomes
e.g. of a sterilization process

Single-use products

- linear manufacturing processes
- mostly used in industry

Multi-use products

- circular manufacturing process
- mostly used in health care setting

Outcome

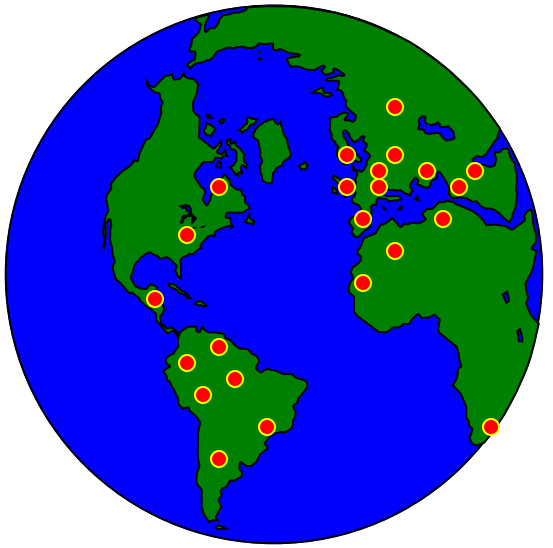
The same:

a sterile product!

Note: all information dated November 2011!

The Standards Organisations
1. National Organisations

- Belgium: nbn
- France: AFNOR
- Germany: DIN
- Netherlands: NEN
- United Kingdom: BSI
- USA: ANSI / AAMI
- …



- Committees populated by experts from industry, academia, user groups & regulatory bodies.

Note: all information dated November 2011!

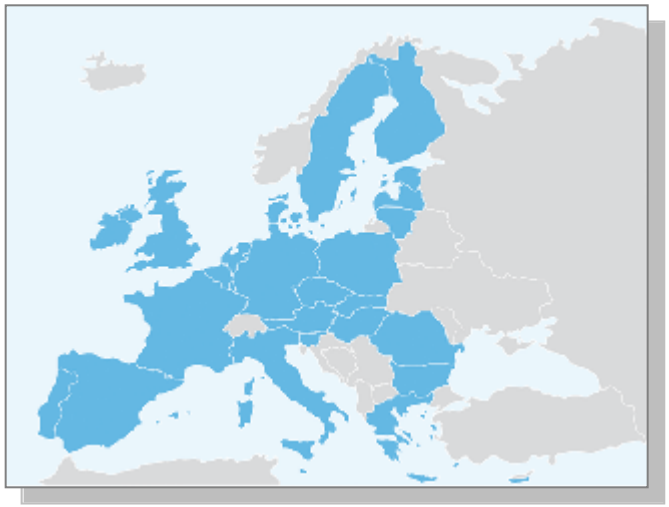
Note: all information dated November 2011!

The Standards Organisations

2. Regional Organisations

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

CEN Management Centre
Avenue Marnix 17
B-1000 Brussels
Belgium
Tel: + 32 2 550 08 11
Fax: + 32 2 550 08 19
www.cen.eu



Committees populated by delegates nominated from each EU countries' standards body.

Note: all information dated November 2011!

Technical Committees

- CEN/TC 102 Sterilizers for medical purposes
  - *Secretariat* *DIN / Fr. A. Müller*
  - *Chairman* *K. Hahnen*
- CEN/TC 204 Sterilization of medical devices
  - *Secretariat* *BSI / Mr D. Upstone*
  - *Chairman* *Dr. E. V. Hoxey*

- Each with several working groups (e.g. large steam sterilizers, indicators, washer/disinfectors, …)

Note: all information dated November 2011!

The Standards Organisations
3. Global Organisations

International Organization for Standardization

International Organization for Standardization (ISO)
1, ch. de la Voie-Creuse,
Case postale 56
CH-1211 Geneva 20
Switzerland
Telephone +41 22 749 01 11
Fax +41 22 733 34 30
www.iso.org

Committees populated by delegates nominated by each countries' standards body.
(mostly Australasia, EU, Japan & North America)

Note: all information dated November 2011!

ISO Technical Committee 198

Sterilization of Health Care products Working Groups

Committee	Title
TC 198/WG 1	Industrial ethylene oxide sterilization
TC 198/WG 2	Radiation sterilization
TC 198/WG 3	Moist heat sterilization
TC 198/WG 4	Biological indicators
TC 198/WG 5	Terminology
TC 198/WG 6	Chemical indicators
TC 198/WG 7	Packaging
TC 198/WG 8	Microbiological methods
TC 198/WG 9	Aseptic processing
TC 198/WG 10	Liquid chemical sterilization
TC 198/WG 11	General criteria for sterilization processes
TC 198/WG 12	Information for reprocessing of re-sterilizable devices
TC 198/WG 13	Washer-disinfectors

Secretariat AAMI / Mr J. Lewelling
Chairman Dr. E. V. Hoxey

Note: all information dated November 2011!

btw: CEN and ISO publish **STANDARDS**

- not laws
- not norms
- not rules
- not …
- CEN and ISO call the documents they publish “standards”, that is how they are addressed in other official documents, that is how they should be called.

sometimes they also publish “Technical Specifications” (e.g. ISO/TS 11139)

Note: all information dated November 2011!

Points to Note

- Standards are voluntary BUT compliance to standards identifies a clear path to regulatory compliance (see Article 5 of MDD).

- ISO standards can be:
  - *adopted as national standards,*
  - *coexist with existing national standards,*
  - *be subject to local variations (national deviations).*

- CEN standards for EU member states have to be:
  - *adopted as national standards,*
  - *adopted unchanged,*
  - *any conflicting local standards must be withdrawn.*

Note: all information dated November 2011!

Medical Device Directive – Article 5

- Under MDD, Medical Devices have to be CE marked when sold in EU and the Essential Requirements must be met.
  - *The essential requirements explain the aim of the Medical Devices Act in that they represent a set of criteria which a medical device must fulfil if it is to be freely traded on the European internal market. The essential requirements give particular consideration to*
    - *the safety*
    - *the technical performance and*
    - *the medical performance of a medical device.*

Note: all information dated November 2011!

Medical Device Directive – Article 5

- Article 5 states that products complying with a harmonised EN are presumed to meet the Essential Requirements of the MDD stated in annex ZA of the particular standard.
- Thus harmonised EN's are very important to medical device manufacturers because they offer a clear cut route to conformity to MDDs & CE marking of product.

Note: all information dated November 2011!

The Vienna Agreement

- An agreement between CEN and ISO to ensure harmonisation of standards published by the two organisations.
- When standards are reviewed under the terms of the agreement, one of the organisations take the lead and revise both sets of standards in a single committee.
- Once finished the resulting document will go out for “parallel voting” which means member bodies in EU will vote for the standard as both an EN and ISO and then adopt said standard as an EN.

Note: all information dated November 2011!

Note: all information dated November 2011!

Terms, Definitions & Information Standards

Note: all information dated November 2011!

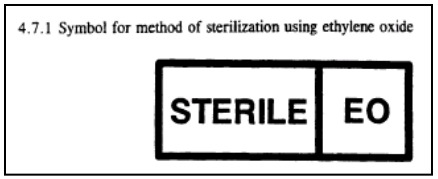
Terms and Definitions I

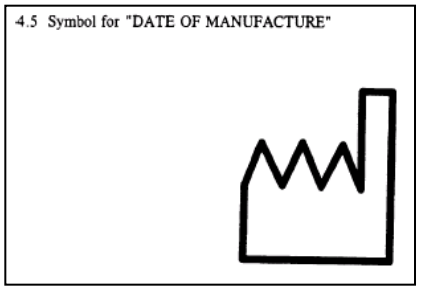
EN 980:2008

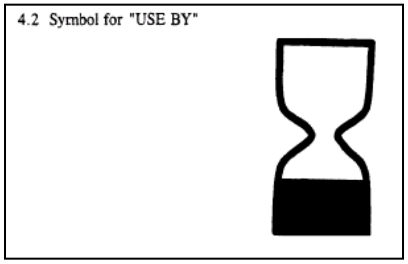
- Symbols for use in the labelling of medical devices

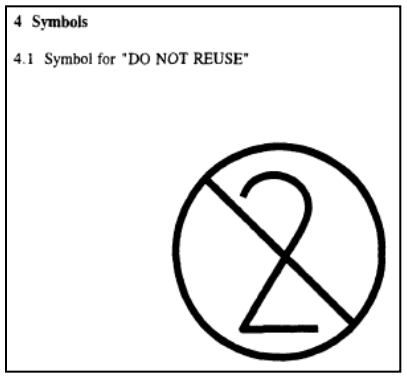
The symbol for **CAUTION** highlights the fact that there are specific warnings or precautions associated with the device

This symbol, for **'KEEP DRY'** is easily recognizable to anyone familiar with the purpose of an 'umbrella.'









Note: all information dated November 2011!

Terms and Definitions II

ISO TS 11139

- Sterilization of health care products – Vocabulary 2nd edition
  - *ISO/TS 11139:2006 gives definitions of terms in the field of sterilization technology.*
  - *ISO/TS 11139:2006 does not provide requirements for the validation and routine control of a sterilization process, but is intended to contribute fundamentally towards mutual understanding amongst those preparing and using International Standards in the field of sterilization technology.*

Note: all information dated November 2011!

Terms and Definitions III

EN ISO 14937:2009

- 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

Note: all information dated November 2011!

Terms and Definitions IV

EN 556-1:2001

- Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

Note: all information dated November 2011!

Information

EN ISO 17664:2004

- Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices

Note: all information dated November 2011!

EN ISO 17664:2004

- EN ISO 17664:2004 specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be resterilizable, and medical devices intended to be sterilized by the processor. EN ISO 17664:2004 specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification.
- Requirements are specified for processing that consists of all or some of the following activities:

  a) preparation at the point of use;

  b) preparation, cleaning, disinfection;

  c) drying;

  d) inspection, maintenance and testing;

  e) packaging;

  f) sterilization;

  g) storage.

Note: all information dated November 2011!

Note: all information dated November 2011!

Quality related Standards I

ISO 9000:2005

- Quality management systems, fundamentals and vocabulary

ISO 9001:2008

- Quality management systems, requirements

Note: all information dated November 2011!

The ISO 9000 family – core standards

- The ISO 9000 standard provides the fundamentals and vocabulary used in the entire ISO 9000 family of standards. It sets the stage for understanding the basic elements of quality management as described in the ISO standards.
- ISO 9000 introduces users to the eight Quality Management Principles as well as the use of the process approach to achieve continual improvement.

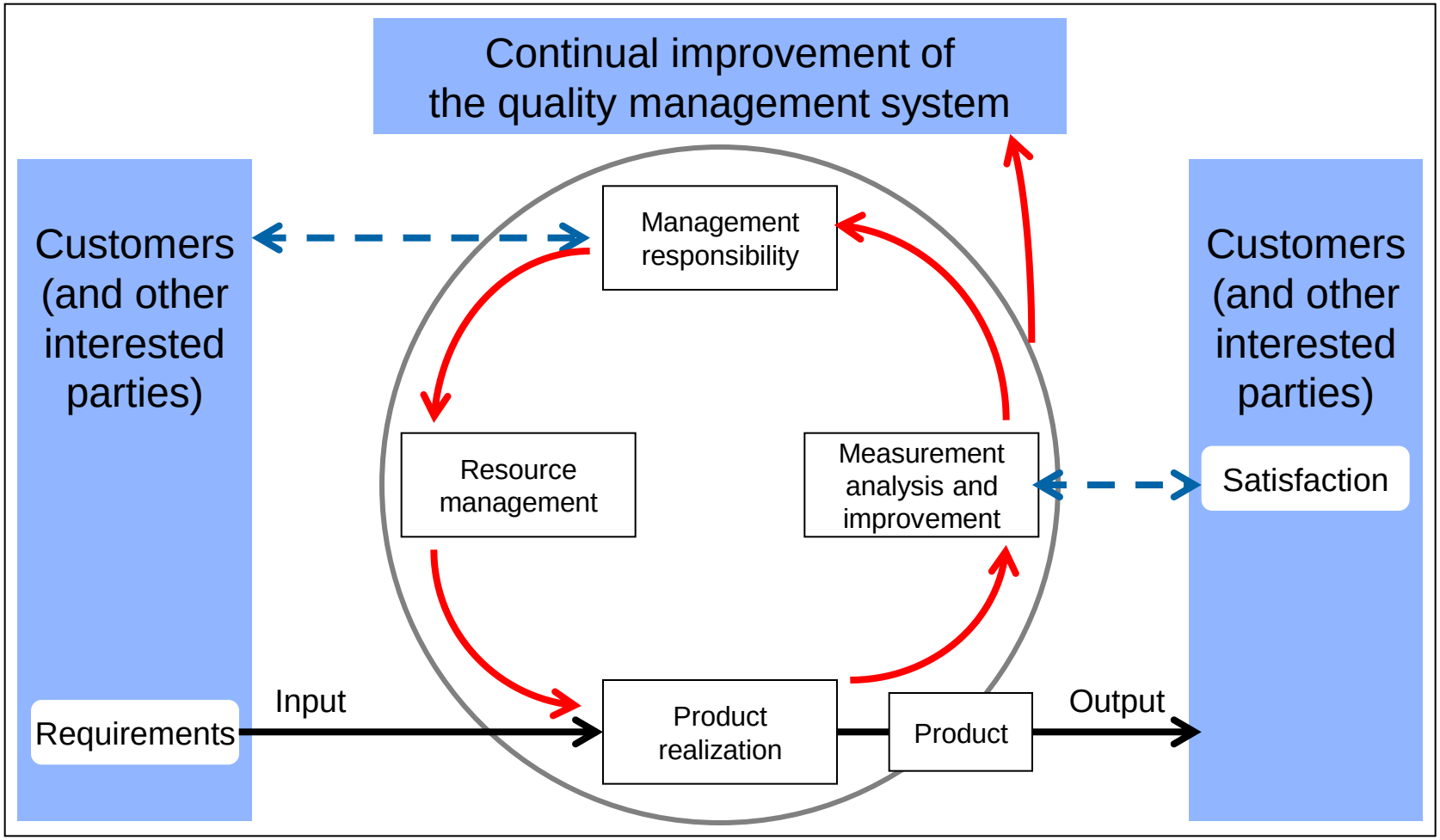
Note: all information dated November 2011!

ISO 9001

- ISO 9001 is used to establish a quality management system
  - *a QMS provides confidence in an organization's ability to provide products that fulfil customer needs and expectations.*
  - *the term "product" applies to services, processed material, hardware and software*
- An ISO 9000 QMS can be certified by an external body
- Five sections specify activities that need to be considered for a QMS:
  - *Overall requirements for the quality management system and documentation*
  - *Management responsibility, focus, policy, planning and objectives*
  - *Resource management and allocation*
  - *Product realization and process management*
  - *Measurement, monitoring, analysis and improvement.*
- A Quality Manual demonstrates how the ISO 9001 requirements are met.
- The five sections of ISO 9001 define what to do to consistently provide product that meets customer, statutory and regulatory requirements.

Note: all information dated November 2011!

ISO 9000 – Continuous Improvement Approach



Note: all information dated November 2011!

Quality related Standards II

ISO 13485:2003

- Medical devices - Quality management systems - Requirements for regulatory purposes
  - *ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.*

Note: all information dated November 2011!

ISO 13485

- *The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.*

- All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization.

Note: all information dated November 2011!

ISO 13485

- *If any requirement(s) in Clause 7 of ISO 13485:2003 is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.*

- The processes required by ISO 13485:2003, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.

Note: all information dated November 2011!

Processing Standards

Note: all information dated November 2011!

Current Processing Standards

- EN ISO 11135 Sterilization by EO
  - *formerly EN 550 & ISO 11135*
- EN ISO 11137 Sterilization by Irradiation
  - *formerly EN 552 & ISO 11137*
- EN ISO 17665 Sterilization by Moist Heat
  - *formerly EN 554, ISO 11134 & ISO 13683*

Note: all information dated November 2011!

Current Processing Standards

- They all have a common format
  - *following that used in ISO 14937*
- The all use consistent definitions
  - *using those defined in ISO TS 11139*
- They all have common quality system elements
  - *based on reference to ISO 13485*

Note: all information dated November 2011!

ISO 14937:2009

- 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

Note: all information dated November 2011!

ISO 14937 – Sections

- Quality system elements
- Sterilizing agent characterization
  - *(Agent definition, microbial effectiveness, material compatibility, safety & environment)*
- Process / equipment characterization
  - *(Process definition, Equipment specification)*
- Product definition
  - *(Product specification, Packaging materials, Product quality prior to sterilization)*
- Process definition
  - *(Development, Biological safety, Process residuals, Product compatibility, re-sterilization)*

Note: all information dated November 2011!

ISO 14937 – Sections

- Validation
  - *(IQ, OQ, PQ, Review and approval)*
- Routine control and monitoring
  - *(Product presentation, Process monitoring, Record generation)*
- Product release from sterilization
  - *(Record Review, Indicator Tests, Product disposition, Corrective action)*
- Maintaining process effectiveness
  - *(Product Quality prior to Sterilization, Calibration, Maintenance, Re-qualification.)*

Note: all information dated November 2011!

ISO 17665 Moist Heat Sterilization

Note: all information dated November 2011!

Standards Involved

- *EN 554 - Validation and Routine Control of Sterilization by Moist Heat*
- *ISO 11134 - Validation & Routine Control – Industrial Moist Heat Sterilization*
- *ISO 13683 - Validation & Routine Control of Moist Heat Sterilization in Health Care Facilities*

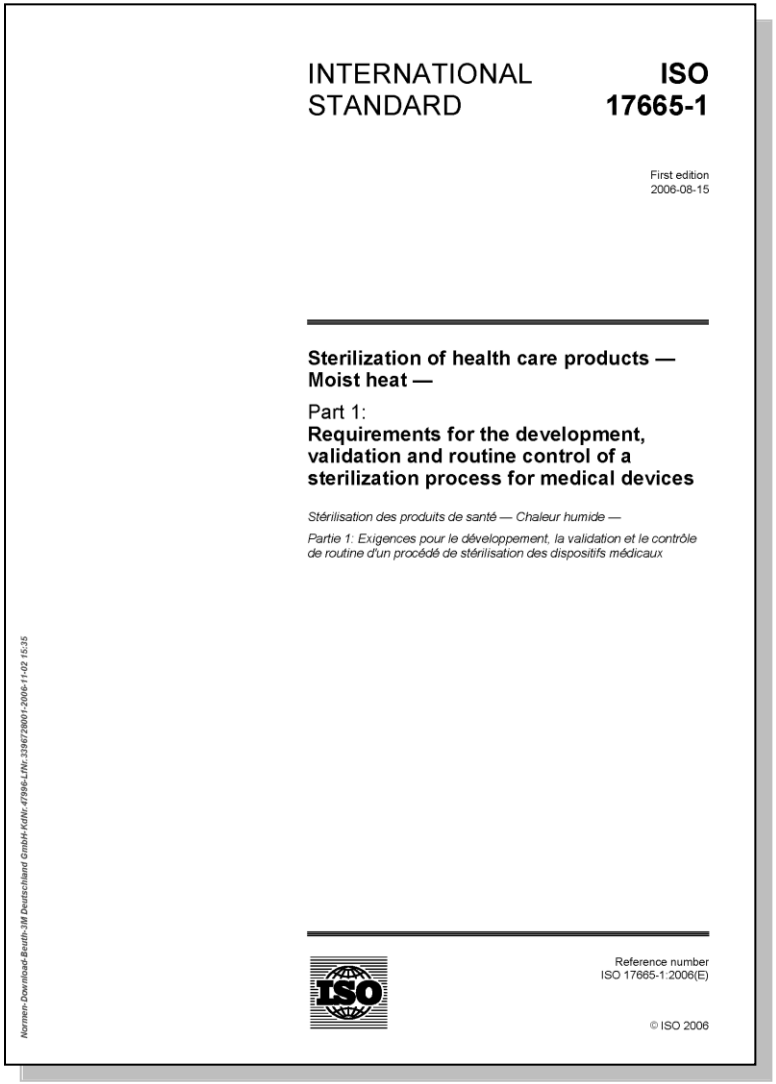
- Have been revised and consolidated into:
  - *ISO 17665*
    Requirements for the development, validation & routine control of sterilization processes for Medical Devices - Moist Heat
    - *a single standard for all moist heat processes used in Pharmaceutical, Medical Device & Health Care*

Note: all information dated November 2011!

Current Status

EN ISO 17665:2006

- **PUBLISHED**
- **Important for EU countries:**
  3 year transition period over since August 2009;
  EN 554 withdrawn
- Guidance published:
  - *ISO/TS 17665-2:2009 Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1*



INTERNATIONAL STANDARD **ISO 17665-1**

First edition
2006-08-15

Sterilization of health care products — Moist heat —

Part 1:
Requirements for the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Chaleur humide —

Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux

Reference number
ISO 17665-1:2006(E)

Note: all information dated November 2011!

ISO 17665 – Scope

- Specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices.
  - *Although the scope of this standard is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other health care products.*

- Moist heat sterilization processes covered by this standard include but are not limited to:
  - a) *saturated steam venting systems* ⇨ Gravity sterilizers
  - b) *saturated steam active air removal systems* ⇨ Pre-vacuum sterilizers
  - c) *air steam mixtures*
  - d) *water spray*
  - e) *water immersion*

  } Industrial (Pharmaceutical)

Note: all information dated November 2011!

Important

- The document is covering diverse processes:
  - *air ballasted processes used in the pharmaceutical industry for flexible IV containers where residual chamber air is essential to prevent product damage*
  - *porous load processes used in hospitals for reusable surgical packs where residual chamber air is dangerous and can compromise attainment of sterility*
- Ensure to use the correct, applicable part for your processes!

Note: all information dated November 2011!

Development of ISO 17665-3

- ISO/DTS 17665-3 - Sterilization of healthcare products – Moist heat
  - *Guidance on the description of a medical device by product family.*

Note: all information dated November 2011!

Product Standards

Note: all information dated November 2011!

EN 285 Large Steam Sterilizers

Note: all information dated November 2011!

Standards Affected

- EN 285 – Sterilization – Steam Sterilizers – Large Sterilizers.
- Has been revised under the 5 year revision rule by CEN TC 102 WG 2/3
- Note : Is not an ISO but a harmonised EU standard.

Note: all information dated November 2011!

Current Status

EN 285:2006

- PUBLISHED
- 2 amendments:
  - *A1:2008 replacing former "rubber load test" by a PTFE test device*
  - *A2:2009 to align document with modified MDD (Medical Device Directive)*

DEUTSCHE NORM August 2009

DIN EN 285

DIN

ICS 11.080.10

Ersatz für
DIN EN 285:2008-06

Sterilisation –
Dampf-Sterilisatoren –
Groß-Sterilisatoren;
Deutsche Fassung EN 285:2006+A2:2009

Sterilization –
Steam sterilizers –
Large sterilizers;
German version EN 285:2006+A2:2009

Stérilisation –
Stérilisateurs à la vapeur d'eau –
Grands stérilisateurs;
Version allemande EN 285:2006+A2:2009

Gesamtumfang 89 Seiten

Normenausschuss Medizin (NAMed) im DIN

Note: all information dated November 2011!

Equipment Standards

- EN 1422
  - *Ethylene Oxide Sterilizers (under revision)*
- EN 13060
  - *Small Steam Sterilizers (under revision)*
- EN ISO 15883:2009
  - *Washer Disinfectors (part 6 “test soils” under revision)*
- EN 14180:2010
  - *LTSF Sterilizers*

Note: all information dated November 2011!

Biological & Chemical Indicator Standards

Note: all information dated November 2011!

Current BI & CI Standards

- EN ISO 11138 – Biological Indicators
- EN ISO 11140 – Chemical Indicators

Note: all information dated November 2011!

Definition of a BI & Scope

- BI – A microbiological test system providing a defined resistance to a specified sterilization process.

- Scope – Covers biological test systems which depend for their function on the demonstration of viability of a test organism (however this is determined).

Note: all information dated November 2011!

EN ISO 11138 – changes from last revision

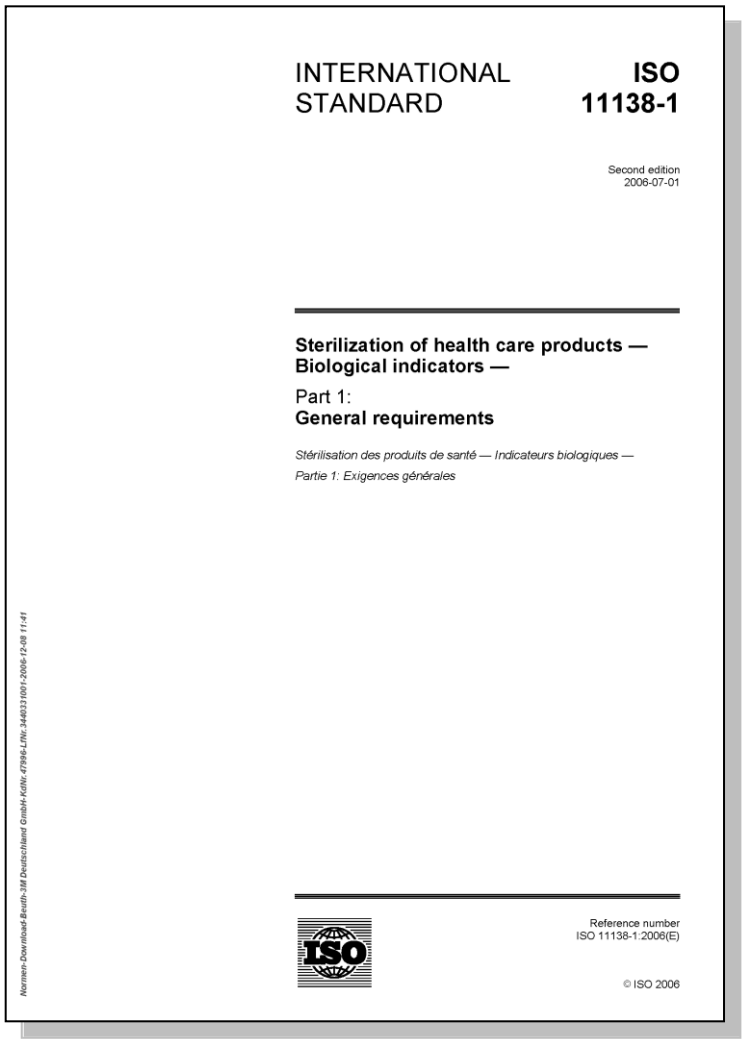
- 2 sets of standards (former EN 866 series and old ISO 11138) have been combined
- Part 4 – Irradiation BI deleted
  - *(Irradiation industry has no need for any reference to BI)*
- Part 7 & 8 deleted
  - *Self Contained parts of EN (7 & 8) combined with parts 2 & 3 of new document.*
- *Bacillus subtilis* renamed to *B. atrophaeus*
- *Bacillus stearothermophilus* renamed to *Geobacillus stearothermophilus*
- New term F_{bio} introduced = D x logP

Note: all information dated November 2011!

BI's – Current status:

EN ISO 11138:2006

- **ALL PARTS PUBLISHED**
  - *Part 1 General requirements*
  - *Part 2 BI's for EO*
  - *Part 3 BI's for Moist Heat*
  - *Part 4 BI's for Dry Heat*
  - *Part 5 BI's for LTSF*



INTERNATIONAL STANDARD **ISO 11138-1**

Second edition
2006-07-01

Sterilization of health care products — Biological indicators —

Part 1:
General requirements

Stérilisation des produits de santé — Indicateurs biologiques —
Partie 1: Exigences générales

Reference number
ISO 11138-1:2006(E)

© ISO 2006

Note: all information dated November 2011!

EN ISO 14161:2009

- Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results
  - *ISO 14161:2009 provides guidance for the selection, use and interpretation of results from application of biological indicators when used in the development, validation and routine monitoring of sterilization processes.*
  - *ISO 14161:2009 applies to biological indicators for which International Standards exist.*

Note: all information dated November 2011!

Definition of a CI & Scope

- CI – System that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.

- Scope – Covers test systems which are not dependent for their action on the detection of the presence or absence of living organisms.

Note: all information dated November 2011!

EN ISO 11140 – changes from last revision

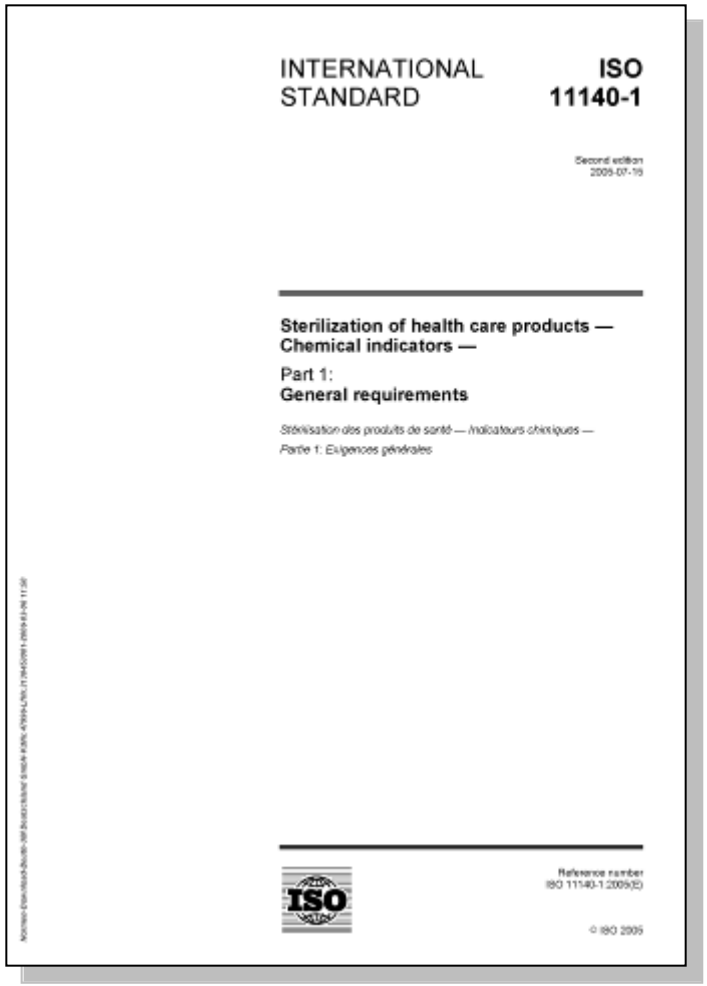
- 2 sets of standards (former EN 867 series and old ISO 11140) have been combined
- ISO 11140-1 contains specific requirements for class 1 & 3, 4, 5 and 6 indicators
  - *This has been combined with parts 1 and 2 of EN 867.*
- ISO 11140-2 has been revised and combined with the BI BIER vessel specification creating a single test vessel standard for testing CI and BI = ISO 18472.
- Classification as per ISO i.e. 1 to 6 (EN 867 was A to D)
- Section covering integrators completely revised to align more closely with function i.e. level of equivalency to biological indicators

Note: all information dated November 2011!

CI's – Current Status

- EN ISO 11140-1
  - *General requirements and classes 1, 3, 4, 5, 6*
  - *Published (in revision)*
- ISO 11140-2
  - *Replaced by ISO 18472*
- EN ISO 11140-3 to 5
  - *"BDT" standards*
  - *Published*

  - *Note: part 5 not accepted by CEN, only ISO!*


INTERNATIONAL STANDARD

ISO 11140-1

Second edition
2009-07-15

Sterilization of health care products — Chemical indicators —

Part 1:
General requirements

Stérilisation des produits de santé — Indicateurs chimiques —
Partie 1: Exigences générales

Reference number
ISO 11140-1:2009(E)

© ISO 2009

Note: all information dated November 2011!

CI classes

- Class 1 – Process Indicators
  - *Used to show exposure to a process. No information about the success or failure of the process*
- Class 2 – Specific Test Indicators (e.g. BDT)
- Class 3 – Single variable indicators
  - *Respond to a single variable in the process e.g. temperature*
- Class 4 – Multivariable Indicators
  - *Respond to two or more variables in the process*
- Class 5 – Integrating Indicators
  - *Respond in a way which mimics the response of a BI if used in the same process*
- Class 6 – Emulating Indicators
  - *Respond to all defined critical variables of the process at levels associated with acceptable sterilizing conditions e.g. 134°C for 5 minutes*

  - ***Important: classification is non-hierarchical!***

Note: all information dated November 2011!

EN ISO 15882:2008

- Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results
  - *ISO 15882:2008 provides guidance for the selection, use and interpretation of results of chemical indicators used in process definition, validation and routine monitoring and overall control of sterilization processes.*
  - *ISO 15882:2008 applies to indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor one or more of the variables required for a sterilization process. These chemical indicators are not dependent for their action on the presence or absence of a living organism.*

Note: all information dated November 2011!

Test Equipment for CI & BI

- The requirements for the test equipment (BIER / CIER vessels) have been deleted from ISO 11138 & 11140 and combined and harmonised into a single new standard, ISO 18472, covering test equipment specification for testing CI and BI.

BIER / CIER at [redacted] Laboratory, Neuss, Germany

Note: all information dated November 2011!

EN 867-5

- Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S
  - *defines a specific porous PCD*
  - *defines a specific hollow PCD*
  - *defines test conditions*
- valid standard
- currently under revision, will re-emerge as EN ISO 11140-6

Note: all information dated November 2011!

Standards on the **WWW**

- http://www.iso.org
  International Organization for Standardization
- http://www.cen.eu
  Comité Européen de Normalisation

Note: all information dated November 2011!