Does your equipment meet your needs and the operational capacity stated by the manufacturer?

Richard Bancroft, B.Sc (Hons)

Registered Authorising Engineer (Decontamination), UK

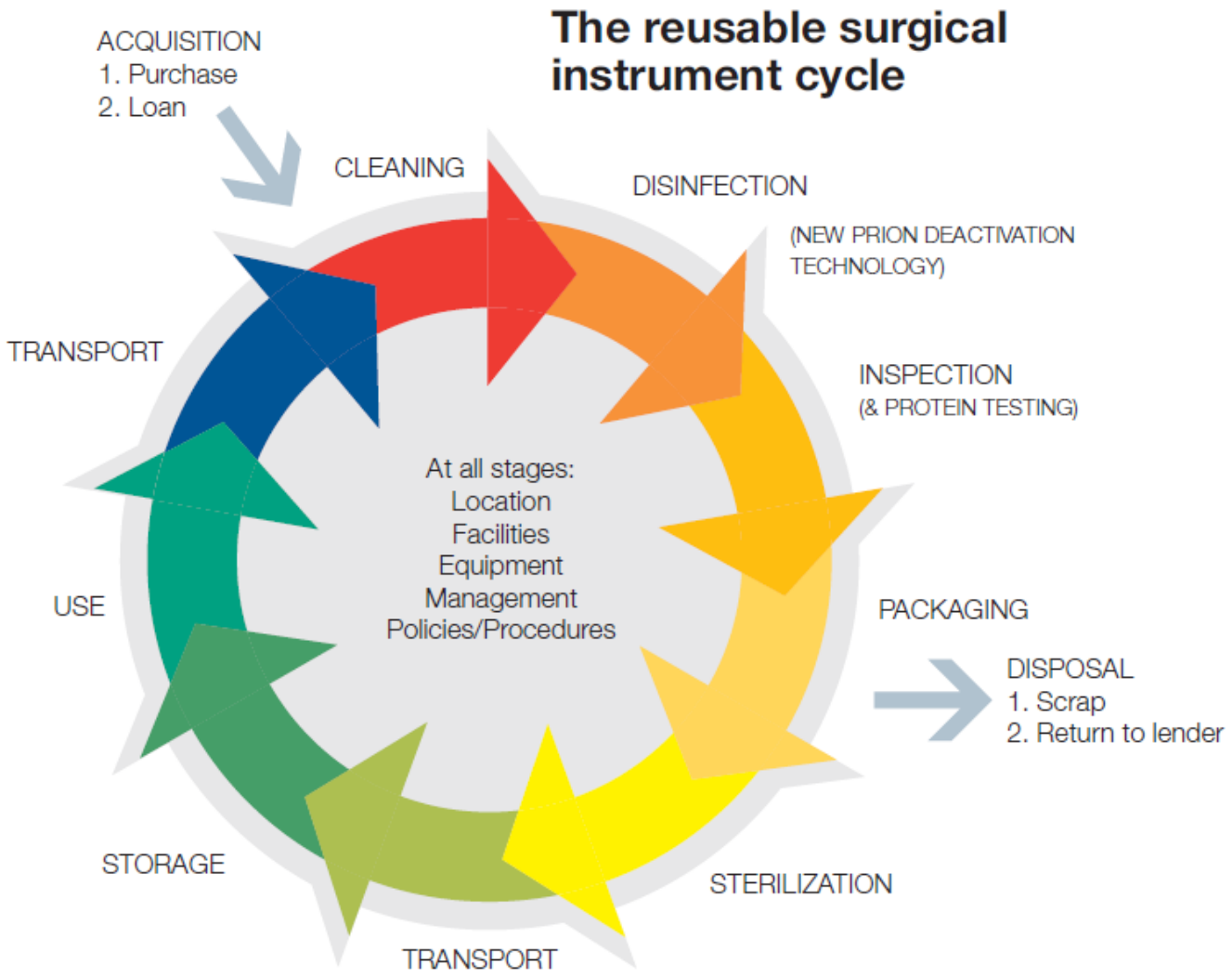
Convenor, ISO/TC 198 WG 6

Convenor, CEN/TC 102 WG 7

Co-chair, AAMI ST/WG 06

Member, AAMI Standards Board

Reprocessing Medical Devices



Reprocessing Stages – Why?

- Clean – to remove proteins and other soils ready for sterilization
- Disinfect – to allow devices to be inspected, assembled and packaged safely by CSSD staff, and ensure bioburden reduction
- Sterilize – to allow devices to be used invasively in safety

Washing – Manual or Automated?

- Manual washing is used either prior to an automated washer-disinfector process or as a sole step prior to sterilization
- This raises three issues:
  - How to validate a manual process?
  - How to monitor a manual process?
  - Lack of disinfection
- Automatic washing and disinfection raises two issues:
  - Validation is required
  - Monitoring is required

Why Do We Need To Monitor Washing?

Washer- Disinfector Issues

- Initial wash temperature too high
- Low detergent concentration
- Misdirected or blocked cleaning jets

Human Factors Issues

- Dried excretions and secretions
- Incorrect loading patterns
- Incorrect detergent
- Immobilised spray arms
- Lack of detergent

Sterilizers

- Sterilizers and associated equipment (such as washer disinfectors) are regulated as <medical devices> or <accessories to medical devices> in many parts of the world
  - In South Africa washer-disinfectors are class B and sterilizers class C medical devices
- This gives specific requirements to their performance
- But how are these requirements practically implemented?

Standards

- Standards are used to create common specifications of performance requirements
- Standards are not usually legal requirements, but conformity to these standards can be used to demonstrate conformity to the legal requirements

Standards Hierarchy

AU	• Therapeutic Goods Act	Europe • Medical Device Directive	USA • 21 CFR
AU	• Medical Device Standards Order	Europe • Harmonisation	USA • FDA Recognition
AU	• Standards	Europe • Standards	USA • Standards
AU	• Guidance Documents	Europe • Guidance Documents	USA • Guidance Documents
AU	• Local Procedures	Europe • Local Procedures	USA • Local Procedures

CEN & ISO standards

CEN Weighted Voting

- 28 Countries of EU, plus EFTA countries
- Voting weighted by size of country (pop)
  - 29 votes for UK
  - 3 votes for Iceland
- Proposal shall be adopted if 71.00 % or more of the weighted votes cast are in favour
  - Abstentions not counted

CEN Weighted Voting

- 29 votes each: DE, FR, GB, IT
- 27 votes each: ES, PL
- 14 votes each: RO
- 13 votes each: NL
- 12 votes each: BE,CZ, GR, HU, PT
- 10 votes each: AT, CH, SE, BG
- 7 votes each: DK, FI, IE, LT, NO, SK
- 4 votes each: CY, EE, LV, LU, SI
- 3 votes each: IS, MT

International Organization for Standardization

- 160 ISO Countries
- 1 country 1 vote
- USA has 1 vote
- United Kingdom has 1 vote
- South Africa has 1 vote

Annex ZA

- Compliance with clauses of a standard (in Table ZA) confers, within the limits of the scope of this standard, a **presumption of conformity** with the corresponding Essential Requirements of that Directive

Annex ZA

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/subclauses of thisEuropean Standard	Essential requirements (ERs)of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 4, 3, 6, 7.1, 8.1, 9.1, 7.2, 9.2	
5.1	2, 7.3	
5.1.3	4	
5.1.7	7.5	
5.1.8	7.5	
5.2	1, 2, 6, 7.1, 7.2, 7.3, 7.5, 8.1, 9.1, 9.2, 9.3, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.4, 12.7.5, 13.1	The WD shall comply with the requirements of IEC 61010-2-045

EN Standards

- EN documents have to be implemented into every EU member state (currently 28 countries)
- They must be implemented unaltered, so no national deviations are permitted
- Any conflicting national standard has to be withdrawn

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

ISO Standards

- There is no requirement to nationally adopt an ISO standard
- They can be nationally modified

International Organization for Standardization

Vienna Agreement

- Agreement on technical cooperation between CEN and ISO of 1991 (Vienna Agreement), revised in 2001

ISO as EN

- An ISO standard can be adopted as an EN standard
- It is then labelled as an EN ISO XXXX
- As an EN it is subject to all the usual EN standard requirements
  - National implementation
  - No national changes permitted

Sterilizer standards

Sterilizer Standards

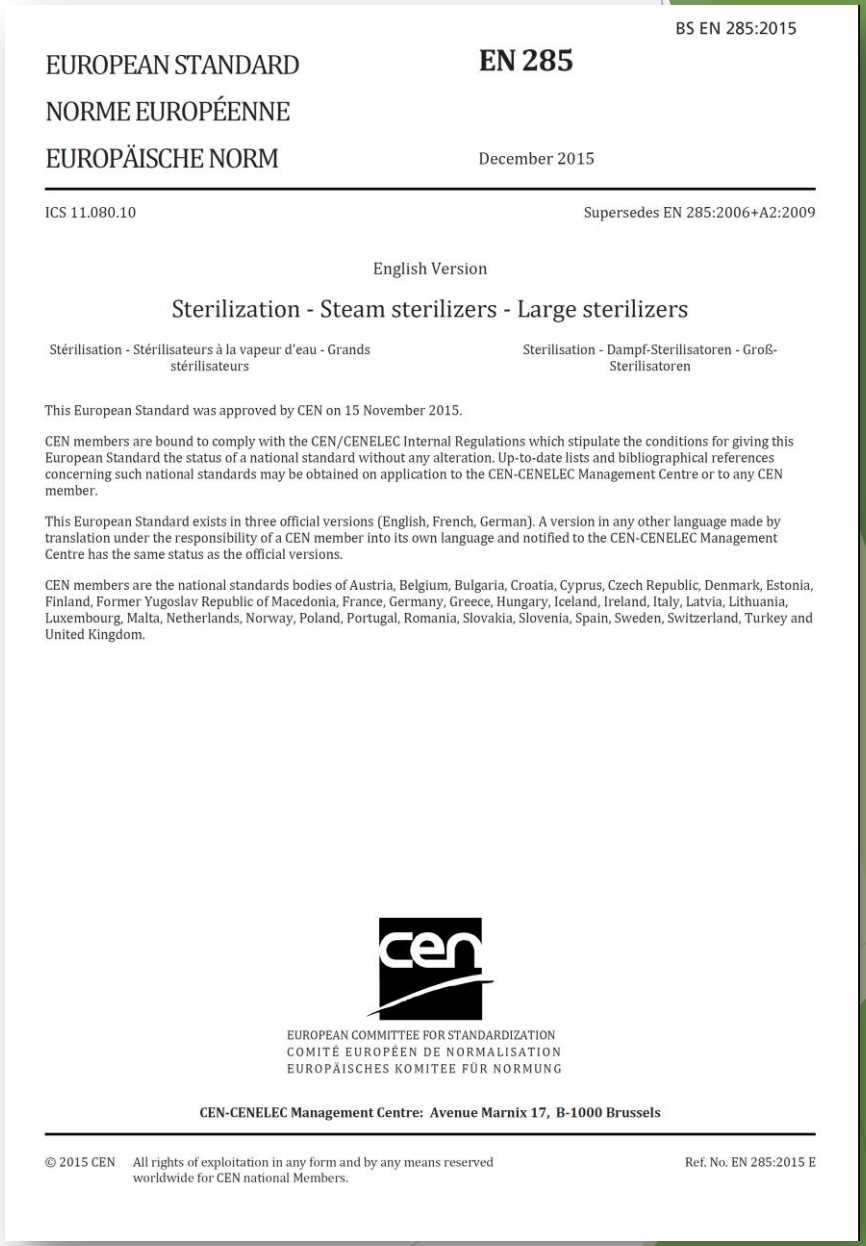
- There are a number of equipment standards for sterilizers:
- Low temperature (for heat labile devices)
  - EN 1422 – Ethylene Oxide sterilizers
  - New CEN work on VH2O2 sterilizers
- High temperature
  - EN 13060 – Small steam sterilizers
  - EN 285 – Large steam sterilizers
- Note they are CEN (and not ISO) standards

EN 285 - Large Steam Sterilizers

- EN 285 first published in 1996
- Major revision in 2006
- Two amendments to 2006 version published in 2008 and 2009
- EN 285:2006 + A2:2009
  - Replacement of the rubber load test (type test) with the EN867-5 helix
- EN 285:2015
  - Latest version

Sterilizer standards in Europe

- EN 285:2015



BS EN 285:2015

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 285

December 2015

ICS 11.080.10

Supersedes EN 285:2006+A2:2009

English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 15 November 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

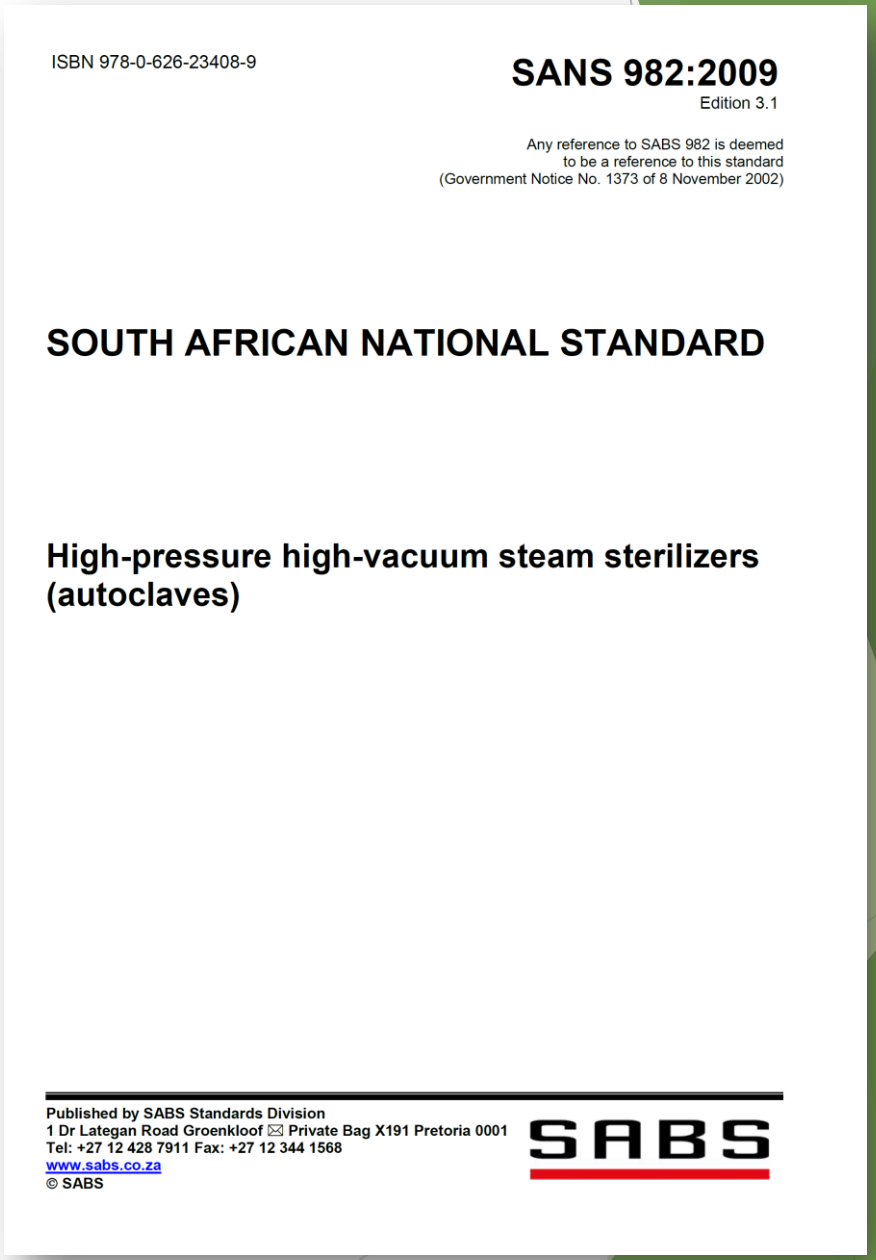
EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 285:2015 E

Sterilizer standards in South Africa

- SANS 982:2009



ISBN 978-0-626-23408-9

SANS 982:2009
Edition 3.1

Any reference to SABS 982 is deemed
to be a reference to this standard
(Government Notice No. 1373 of 8 November 2002)

SOUTH AFRICAN NATIONAL STANDARD

High-pressure high-vacuum steam sterilizers (autoclaves)

Published by SABS Standards Division
1 Dr Lategan Road Groenkloof ✉ Private Bag X191 Pretoria 0001
Tel: +27 12 428 7911 Fax: +27 12 344 1568
www.sabs.co.za

SABS

Common requirements between EN 285 and SANS 982

- SANS 982 has 18 pages
- EN 285 has 102 pages

Comparison between EN 285 and SANS 982

- EN 285 has no specific requirement differences between sterilizers connected to house steam or integral electric steam generators
- SANS 982 specifies type A (independent steam supply) and type B (electric steam generator)

Comparison between EN 285 and SANS 982

- EN 285 has a specific requirement to state the usable chamber size by way of sterilization modules (300mm x 300mm x 600mm)
- SANS 982 has no requirement to standardise chamber sizes

Comparison between EN 285 and SANS 982

- EN 285 has a requirement for a minimum vacuum level to be attained of 7 kPa (70 mbar); there is no minimum time to attain this value
- SANS 982 has a minimum vacuum requirement of 20kPa (200 mbar) within 3 mins

Comparison between EN 285 and SANS 982

- EN 285 has a requirement for a 3˚C sterilization temperature band; typically this is 134˚C to 137˚C
- SANS 982 has a requirement of a sterilization temperature band of 134˚C to 138˚C

Comparison between EN 285 and SANS 982

- EN 285 has a requirement for filtered air to be better than 0.3µM
- SANS 982 has a requirement for filtered air to be better than 3µM

Comparison between EN 285 and SANS 982

- EN 285 has no requirements for the number of air removal pulses – only that tests such as the small load thermometric test shall be passed
- SANS 982 has a requirement for ≥4 air removal pulses

Comparison between EN 285 and SANS 982

- EN 285 has a requirement for the sterilization hold period of greater than or equal to 3.5 mins
- SANS 982 has a requirement for the sterilization hold period of greater than or equal to 4 mins up to a maximum of 20 mins

Comparison between EN 285 and SANS 982

- EN 285 has no requirement for how long steam admission can take, but does have a requirement for the equilibration time of ≤15 seconds
- SANS 982 has a requirement for the steam admission stage to be ≤6 minutes, but no equilibration time

Comparison between EN 285 and SANS 982

- EN 285 has a requirement for the leak rate test for the leakage to be no greater than 1.3kPa over 10 mins
- SANS 982 has a requirement for the leak rate test for the leakage to be no greater than 1.33kPa over 10 mins

Comparison between EN 285 and SANS 982

- EN 285 has a number of requirements to successfully pass specific type tests, e.g. small load and full load thermometric tests, load dryness tests etc, and reference to ISO 17665 for sterilization
- SANS 982 has no requirements for sterility other than the requirement to pass the Bowie Dick steam penetration test

EN 285:2015 Type Test

- Hollow load test (Helix) type test
- ‘not intended to be used as a routine daily test’

Hollow load test [b]	8.2.5	Clause 15	—	XX
Bowie and Dick test	8.2.3	Clause 17		XX

a Compliance tested in accordance with acknowledged analytical methods.

b This test is not intended to be used as a routine daily test.

c If an air detector is fitted (see 8.2.4.1).

Equipment Standards vs Process Standards

- A sterilizer is considered a piece of equipment (as well as a medical device)
- It is required to perform in a specified way and deliver a process
- The validation of that process is specified in a different standard

EN ISO 17665

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

EN ISO 17665

- EN ISO 17665-1 replaced EN 554, ISO 11134 and ISO 13683 in 2006
- EN ISO 17665-1 specifies methods for validation and routine control for moist heat (steam) sterilization
- Validation – IQ, OQ & PQ

EN ISO 17665 - Developments

- Revision of EN ISO 17665-1 will begin in April 2017
- ISO/TS 17665-2 guidance will be merged with part 1
- Consideration of adding ISO/TS 17665-3 into part 1 too

ISO/TS 17665-2

- ISO/TS 17665-2 was first published in 2009
- It gives practical guidance on the implementation of EN ISO 17665-1 for moist heat sterilization
- Will be merged with ISO 17665-1 during upcoming revision

ISO/TS 17665-3

- Requirements on product families to be used during PQ
- Provides guidance for the attributes of a medical device that should be considered by the User, when assigning a medical device to a product family, for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process

Declaration of Conformity

- Sterilizers and other equipment can be shown by manufacturers to comply to standards by way of a declaration of conformity (DoC)
- Partial conformity is an oxymoron
- Beware manufacturers that claim conformity and then provide exceptions to requirements

The Future…

- ISO is working on a ‘common requirements for sterilizers’ standard
- South Africa (as ISO TC 198 members) will be able to participate in this work
- The standard will initially sit alongside national and regional sterilizer standards

Conclusion

- There are much more detailed requirements in EN 285 than in SANS 982
- Should the sterilizer and process requirements in South Africa be raised to that of other parts of the world?
- Should South Africa adopt EN 285 and ISO 17665?

Thank you

Richard Bancroft, B.Sc (Hons)
Richard_Bancroft@steris.com
Science & Technical Director
STERIS Corporation
Registered Authorising Engineer (Decontamination), UK
Convenor, ISO/TC 198 WG 6
Convenor, CEN/TC 102 WG 7
Co-chair, AAMI ST/WG 06
Member, AAMI Standards Board