

UK Decontamination Experts share their Views on the SANS/ISO 17665-1 Standard

Paul Holland and Peter Hooper recently visited South Africa to lecture at the Advanced Course on Sterile Services Management at Stellenbosch University in Cape Town. While they were here SteriView asked them some questions about the ISO 17665-1 Standard for the Sterilization of Healthcare Products by Steam, which South Africa has adopted. A brief description of this standard is included on Page 2 of this newsletter for information purposes.



Paul Holland has a MA Degree in Healthcare Risk Management. He has over 20 years experience in Sterile Supply and Decontamination Management with the National Health Service in the UK. He is employed by the Kingston Hospital National Health Service Trust. He is a Past National Chairman of the Institute of Decontamination Sciences (formerly the Institute of Sterile Services Management) in the United Kingdom.



Peter Hooper, is an Authorising Engineer (Decontamination) from Banbury, UK and is the current Editor of Zentral Sterilisation, the International Journal of Sterile Supply.

SV

What does Product Traceability mean in terms of the ISO 17665-1 standard?

PH

ISO 17665-1 paragraph 4.3.2 simply directs the reader to "the applicable clause in ISO 13485" which in turn quotes ISO 9001, section 4.8. However, 13485 section 4.8 b) Traceability states "The supplier shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and shall facilitate corrective and preventative action (see 4.14)"

SV

Would the "supplier" referred to in ISO 13485 also mean a Healthcare Facility that does its own reprocessing?

PH

Yes, that is correct.

SV

What are the main elements of a Product Traceability system?

PH

That it should deliver what your quality policy documents state you aim to achieve, and in terms of Europe, meet the requirements of the MDD (Medical Devices Directive 93/42/EEC) if the facility is placing product on the market.

SV

What should be covered in a Healthcare Facility's quality policy documents?

PH

They would typically comprise the Quality Manual which would reflect how the facility meets for example ISO 13485 and the MDD, the Quality Control Procedures Manual which comprises the procedures the department follows to deliver what it states in the Quality Manual, Standard Operating Procedures and the Technical File which covers how the facility complies with the Essential Requirements of the MDD and other relevant information on product realization.

SV

Does the standard require hospitals to be able to trace individual instruments or is it sufficient to track sets of instruments?

PH

This question is not relevant to ISO 17665. In the UK the requirement is that all sets should be traceable through the decontamination process to the patient they are used on. Individual instrument identification, either singly or within sets, is required in specialties where there are particular concerns associated with potential iatrogenic transmission of vCJD e.g. neuro, posterior eye and spinal surgery. (See NICE guidelines).

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SV

What does Validation mean in terms of the ISO 17665-1 standard?

PH

I would first of all like to state that these answers are a personal interpretation of the Standard's content and should not be taken as definitive. Validation is similarly defined in this and other Standards as a method for confirming that a sterilizer is constantly able to produce product meeting the requirements of its specification. It is a sequential process that must be documented enabling an informed decision based on recorded results to establish acceptability. In other words, it always does what it is supposed to.

SV

What is the difference between Validation and Qualification?

PH

In theory validation is performed at installation but may be repeated at a later date if there is a need for it to be repeated after, say, a major repair or a major component replacement. Qualification should be accompanied by a descriptive word indicating which part of the equipment or system is being validated e.g. the installation, the machine's operational function or its performance on particular loading arrangements. A repeat validation can be called a requalification. It is assumed that periodic testing will be covered in part 2.

SV

Who is responsible for the three different types of Qualification (IQ, OQ and PQ)?

PH

The Standard does not answer this question. My personal opinion is that whoever they are they should be trained, competent and certified.

SV

What are product specifications and operating procedures?

PH

The specification is the blueprint for the end result required from the sterilizer. Its performance is designed around this. Operating procedures amount to an instruction manual for the sterilizer and any/all associated devices, procedures and methods

SV

Do the persons carrying out the qualification need to have any special training or accreditation?

PH

As I mentioned above, the Standard does not answer this question. It should be remembered that further details on this and associated issues may appear in part 2 of this Standard though there may be versions of that part specific to certain geographical regions. This possibility is awaited with some interest.

SV

Who is responsible for reviewing and approval of validation?

PH

The Standard does not define who reviews or approves the validation process but cross references eventually take you to a Quality Systems Standard, compliance with which is an aspiration of the Standard.

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A Review of the SANS/ISO 17665-1 Standard for the sterilization of Healthcare products by Steam

The above international standard, the full title of which is SANS/ISO 17665-1:2007/ ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, was adopted by South Africa in 2007.

SANS/ISO 17665-1 is the basic standard for sterilization with moist heat; it describes the current state of the art, and it will replace the existing standards for medical devices in industrial and healthcare facilities at the end of a 30-month transition period.

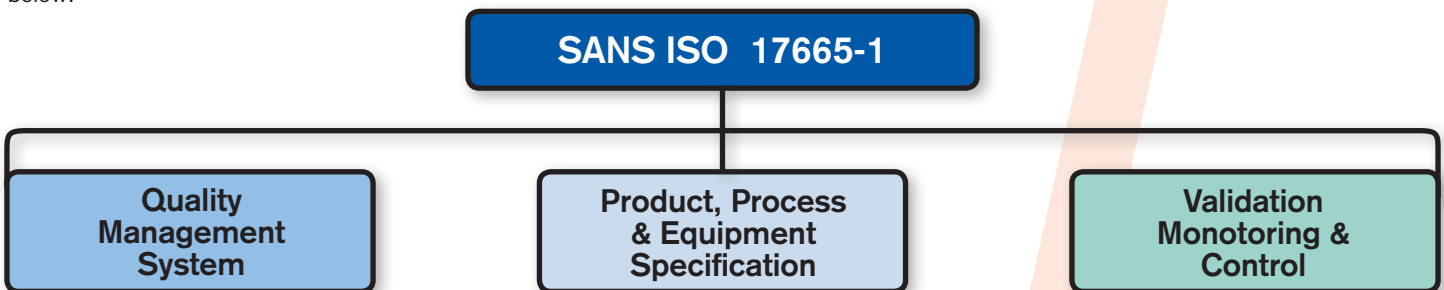
The standards that will be replaced are as follows:

- EN 554 (Sterilization of Medical Devices – Validation and routine control of sterilization by moist heat)
- ISO 11134 (Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization) and
- ISO 13683 (Sterilization of healthcare products—Validation and routine control of moist-heat sterilization in healthcare facilities)

SANS/ISO 17665-1 is valid for sterilization of solid (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. SANS/ISO 17665-1 is thus also valid for sterilization with small steam sterilizers in the field of dentistry.

Generic requirements for the quality management of design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485.

It has been recognized, however, that for certain processes used in manufacturing, such as sterilization, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained. This is why the standard SANS/ISO 17665-1 was developed and it calls for a detailed description of all conditions affecting the process performance. These are illustrated in the diagram below:



Quality Management System Elements

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

Product, Process and Equipment Specification

The standard requires the manufacturer or healthcare facility to define the product to be sterilized, including the microbiological quality of the product prior to sterilization (bioburden) and the manner in which the product is packaged and presented for sterilization.

This essentially means in the context of sterile reprocessing in the hospital setting that it is necessary to obtain detailed reprocessing instructions from the medical device manufacturer. This should include detailed disassembly, cleaning, assembly, packaging and sterilization instructions.

Validation

The purpose of validation is to establish that the sterilization process developed in process definition can be delivered effectively and reproducibly to the sterilization load. Validation consists of a number of identified stages:

- Installation qualification,
- Operation qualification and
- Performance qualification.

Routine monitoring and control

The purpose of routine monitoring and control is to ensure that the validated sterilizing process has been delivered to the product. This is evidenced from data obtained during the sterilization process and from periodic tests used to verify that the specified sterilization process can be delivered.

157 Hospitals benefit from SafMed's CSSD Training Programme

The SafMed Foundation Course in Sterilization and Decontamination is not product related and is offered free of charge to anyone working in the Sterile service environment. It is aligned with the Stellenbosch University Sterilisation and Decontamination Course meeting the entry requirements for admission to the Stellenbosch University Basic Course in Sterilization and Decontamination.

SafMed ran the first Foundation Course Workshop at Mowbray Maternity Hospital in Cape Town in December 2006. Since then SafMed has trained 857 people from 157 hospitals throughout Southern Africa, with a 90% pass rate. Sixteen workshops were sponsored in 2008 alone. Four Stellenbosch University Basic Courses have been sponsored in the past two years, 91 students have been trained with a 90% pass rate. Due to demand SafMed also sponsored a Basic Course in Pretoria during 2008.

SafMed has been offering training free of charge in the area of Sterile Services for the last 15 years. As part of SafMed's contribution to the community, the Company decided in 2006 to create a training post and employ an expert in the field of hospital sterile services to specifically set up and run courses in the Sterile Service area. This course is offered free of charge to anyone that works in the sterile services environment where infection control and specifically decontamination is paramount. In order to understand and meet the needs of the CSSD, SafMed has worked closely with the Western Cape, Gauteng and KwaZulu CSSD Forums when organising courses.

Denise, the SafMed Training Officer, is a qualified Nursing lecturer with 20 years lecturing experience behind her. She has taught in the UK, Johannesburg and Cape Town becoming an expert in the field of sterile services. Denise has written a CSSD manual specifically aimed at South African CSSD's which is handed out free of charge to those students attending the basic Course, 88 manuals have been given to students.

SafMed has agreed to second Denise to the University of Stellenbosch where she has assisted Professor Mehtar in running the Basic Course in Sterilization and Decontamination, since 2007.

The SafMed Foundation Course in Sterilization and Decontamination is a brief orientation to all aspects of the CSSD. It takes the form of a 5-hour workshop with a short 30-minute competency exam at the end. In order to be issued with a SafMed certificate, students must attain at least 80%. Details of the training programmes for 2009 can be seen on the back page of this newsletter.

Foundation Course in Decontamination and Sterilization

The **SafMed Foundation and Advanced Foundation Courses in Sterilization and Decontamination** give a brief orientation to all aspects of the CSSD. As part of SafMed's contribution to the community, this course is offered free of charge to anyone that works in the sterile services environment where infection control and specifically decontamination is paramount.

The Advanced Foundation Course aimed specifically at Managers and Supervisors, runs over 2 days, and has a practical component on risk assessment.

The Foundation Course is a 5-hour workshop with a short 30-minute competency exam at the end. In order to be issued with a SafMed certificate, students must attain at least 80%.

The Foundation Course will cover the following:

- History of Sterile Services
- Standard of Care and Legal Implications
- Infection Prevention
- The Decontamination and Sterilization Process
- The Principles of Cleaning
- Principals of Inspection of Medical Devices
- Principles of Assembly and Packaging
- Steam Sterilization Practice
- Storage and Distribution

The Advanced Foundation Course will cover the following:

- Relevant Legislation
- Health and Safety assessment
- Basic Microbiology
- Sterilization Methods
- Monitoring, Tracking and Recording
- Risk Assessment
- Quality Assurance

Contact Information

In order to attend these courses an application form must be submitted, which can be obtained from SafMed's co-ordinators, as follows:

Charmaine Fraser (Cape Town)

Tel: 021 763 3280

Email: charmaine@safmed.co.za

Annie Pillay (Johannesburg)

Tel: 011 201 4321

Email: annie@safmed.co.za

For further information on course content please contact Denise Sheard

Email: denise@gfc.co.za

Training courses for 2009

Course	Venue	Provisional Dates	Deadlines for Applications
Foundation Course in Sterilization and Decontamination	Gauteng	16 Mar	2 Mar
Advanced Foundation Course in Sterilization and Decontamination	Free State	18/19 Mar	2 Mar
Advanced Foundation Course in Sterilization and Decontamination	Gauteng	1 / 2 June	15 May
Foundation Course in Sterilization and Decontamination	Limpopo	4 June	11 May
Foundation Course in Sterilization and Decontamination	Mpumalanga	24 Oct	12 Oct
Foundation Course in Sterilization and Decontamination	Cape Town	4 Apr	23 Mar
Foundation Course in Sterilization and Decontamination	Cape Town	3 Nov	26 Oct
Foundation Course in Sterilization and Decontamination	Port Elizabeth	6 Jul	29 Jun
Foundation Course in Sterilization and Decontamination	Durban	11 Aug	27 Jul

Interview with Paul Holland

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With regard to the MDD, requirements for product traceability and recall are defined, how the facility complies with that requirement is up to them.

SV

Is the standard very prescriptive on how a Product Traceability system needs to be implemented or can hospitals design their own systems in order to comply with the standard?

PH

Where the MDD is applicable, it is up to the service provider to develop a solution which meets the MDD essential requirements. Other relevant national guidelines may apply, and if so, need to be covered within the solution deployed.

SV

What system do you use in your hospital and why did you choose this particular system?

PH

We are currently developing a business case for a computerized system. We believe that a computerized system will allow us to manage our processes more efficiently and access data much quicker.

SV

What recommendations would you make to a hospital that wishes to implement a Product Traceability system?

PH

Do it, it's essential for patient and staff safety.

Interview with Peter Hooper

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It is likely therefore that the definition will be within the constraints of ISO 13485, for the organization operating that Standard to define and designate.

SV

Why is it necessary to specify product families, load configurations, size of sterilization loads, descriptions of packaging systems and methods etc for a sterilization process?

PH

The concept of load families is in my opinion, a means of allowing the user to define the type or types of loads to be processed, enabling the specification to be, well specific. Categorizing many load variation into families may allow a more practical amount of performance qualification tests to be performed. There is thus a responsibility on the person defining the families to ensure that they are representative of each individual configuration. Again, this will be part of the specification.

SV

Does this mean that a hospital is not allowed to sterilize loads that are not pre-specified?

PH

A hospital should always be very clear about what load types and thus individual components of those load types will require reprocessing. The skill is in defining the families to cover the (wide) variety of load items reflecting real-life reprocessing. Every load should be specified to be within a family.

SV

South African hospitals have a long way to go in terms of implementing ISO 17665-1. What recommendations would you make as to where they should start with the process?

PH

I am tempted to say wait until part 2 is published, then treat the document as a whole but that would be a denial of part 1. Hospitals in South Africa will need to digest the need for an approach to sterilization that treats a sterilizer as a tool to sterilize a specific load or loads, rather than a universal item of equipment that can meet any obstacle. The sterilizer then becomes a link in a chain made up of pre-determined stages for particular ends. Understanding this concept is probably the most important thing to learn.

Review of the SANS/ISO 17665-1 Standard for the sterilization of Healthcare products by Steam

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The standard requires that routine monitoring and control shall be performed on each operating cycle and that evidence of successful maintenance and requalification (if applicable) shall be verified. The operational status of the equipment (if applicable) shall be verified by evidence from periodic tests of factors such as (but not limited to) the following:

- Air leakage into the sterilizer chamber;
- Quality of saturated steam admitted to the sterilizer chamber (which may include checks for non-condensable gas, conductivity of feed water, contaminant(s), moisture content);
- Automatic control (e.g., a test to verify that the operating cycle continues to function correctly);
- Steam penetration;
- Sterilization process (e.g., a test to verify that the sterilization process remains reproducible).

Delivery of the sterilization process shall be verified from the result of chemical indicators and biological indicator systems, if used, and by confirming that within specified tolerances, recorded data from routine monitoring match data from validation.

For saturated steam processes, the data shall include (if applicable):

- Sterilization temperature, chamber pressure and theoretical steam temperature during the plateau period;
- Duration of the plateau period;
- The chamber temperature and the chamber pressure for each stage of the operating cycle;
- The results obtained from a Process Challenge Device
- Temperatures and/or pressures in a process monitoring system, if used as part of process control.

All documents and records shall be reviewed and approved by designated personnel. Documents and records shall be controlled in accordance with the applicable clauses of ISO 13485.

While the standard gives the expert tremendous discretionary powers, an Informative Guide ISO/TS 17665-2 will be published in the near future, which will give explanations, examples and a description of appropriate methods for uniform interpretation and implementation of ISO 17665-1.

The logo for SafMed (Pty) Ltd. The word "SafMed" is written in a bold, sans-serif font. "Saf" is in blue and "Med" is in red. Below the logo, the text "SafMed (Pty) Ltd" is written in a smaller, blue font.

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