Danish Standard for CSSD
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Background

- The Danish Standardisation Committee S-354 developed in 1999-2003 a series of standards with requirements for infection control in the health sector
  - One system requirement standard (DS 2450) and twelve standards with infection control requirements
- This proposal is intended to be no. 13 in the national DS 2451 series covering CSSD
- Working Group:
  - Steffen Strøbæk (chairman of S-354 and WG)
  - Annelise Erichsen
  - Regina Hansen
  - Pia Hilsberg
  - Mette Helmig von der Osten
Application of the standards

- The series of infection control standards is still not mandatory for Danish hospitals.
- A National Danish Accreditation Scheme for the Health Sector is under establishment.
- The intention is that the infection control standards shall support the accreditation scheme.
- The standards have been used in combination with the standards of Joint Commission and Health Quality Service as well as EN ISO 9001:2000 (CEN/TS 15224:2005).
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The organisation shall establish a infection control system fulfilling the requirements of DS 2450:2001 (derived from EN ISO 9001:2000)

Additional system requirements:
- The CSSD shall be included in the organisational chart of the (hospital) organisation to define responsibility hierarchy
- Specifications, product and customer lists shall be documented
- Equipment to be processed by the CSSD shall be identifiable and traceable
- The degree of traceability shall be based on risk assessment
- Early warning system
- Vigilance reporting to authorities
ISO 9001
DS 2450

Management responsibility

Control of documents

Continual improvement

Ressource management

Measurement, analysis and improvement

Infection control procedures

Product and service realisation

Discharge

Admission

Fulfilment of req.

Req. of interested parties

Planning
Communication
Development
Purchase
Diagnosis
Prevention
Examination
Treatment
Care
Rehabilitation

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Risk assessment

Risk factor

CCP

Within critical limits?

Harm

Yes

Reduced hazard

No

Increased hazard

Hands, wrists, forearms

When?

Procedure

Before clean and after contaminated activities

At least 2 ml hand disinfectant shall be applied and rubbed on each finger, between fingers and on back of hand, palm and around wrist
Risk factors (1)

- 4.4.1 Receipt and storage of clean/sterile product at the site of use before use
- 4.4.2 Handling of unclean/used products on the site of use after use
- 4.4.3 Storage of unclean/used products on the site of use after use
- 4.4.4 Internal and external transport of unclean/used products from the site of use to the CSSD
- 4.4.5 Receipt and storage of unclean/used products on intermediate storage
- 4.4.6 Receipt and storage of unclean/used products in the CSSD
- 4.4.7 Inspection and pre-treatment of unclean/used/new/renovated products in the CSSD
- 4.4.8 Inspection, laying up, packaging and labelling of clean products in the CSSD
Risk factors (2)

- 4.4.9 Sterilisation and/or inspection and release of clean/sterile products in the CSSD
- 4.4.10 Transport of inhouse processed clean/sterile products to sterile storage
- 4.4.11 Storage of clean/sterile product in coarse storage of the CSSD
- 4.4.12 Transport of clean/sterile product from coarse storage to sterile storage
- 4.4.13 Removal of tertiary packaging layer
- 4.4.14 Storage of sterile product in the sterile storage of the CSSD
- 4.4.15 Transport of clean/sterile product from the CSSD to the site of use
- 4.4.16 Receipt and storage of clean/sterile products in the coarse storage
- 4.4.17 Receipt and inspection of purchased goods and new/renovated products and transportation to storages /pre-treatment area
Critical Control Points (CCPs)

- Behaviour of staff members
- The physical environment
- Production processes
- Production equipment
Categories of critical limits

- 4.4.X.1 Staff
- 4.4.X.2 Working suit
- 4.4.X.3 Hand hygiene
- 4.4.X.4 Behaviour
- 4.4.X.5 The physical environment
- 4.4.X.6 Transport equipment
- 4.4.X.7 Transport routes
- 4.4.X.8 Product inspection
4.4.6 Receipt of unclean/used products in the CSSD

4.4.7 Inspection and pre-treatment of unclean/used/new/renovated product in the CSSD

4.4.8 Inspection, laying up, packaging and labelling of clean product in the CSSD

4.4.9 Sterilisation and/or inspection and release of clean/sterile products in the CSSD

4.4.17 Receipt and inspection of purchased goods and new/renovated products and transport to storages/pre-treatment area
Example: 4.4.9 Sterilisation... (1)

- **4.4.9.1 Staff**
  - Persons with communicable diseases or skin diseases/lesions in not covered parts of the body **should** not participate in receipt and storage activities
  - By symptoms of communicable diseases or skin diseases/lesions in not covered parts of the body, a competent person **shall** decide on dismissal from work or allocation to other work activities
4.4.9.2 Working suit
- dress code should be defined
- a clean working suit shall be put on at start of working period
- the working suit shall fulfil the requirements the standard DS 2451-8
- the working suit shall be changed, if contaminated
- an operation cap shall be worn
Example: 4.4.9 Sterilisation… (3)

- **4.4.9.3 Hand hygiene**
  - Hand hygiene **shall** be performed according to DS 2451-2

- **4.4.9.4 Behaviour**
  - Rules for behaviour **should** be defined
  - Eating, drinking and smoking in the working area **shall** not be allowed
  - Private possessions **should** not be present
  - Movements **should** be at a slow pace
Example: 4.4.9 Sterilisation… (4)

- **4.4.9.5 The physical rammer**
  - Accession rules should be defined
  - The air change shall be at least 10 times per hour
  - The humidity should be 30-60% rH
  - The temperature should be maximum 24°C
  - The air pressure shall be higher than in the surroundings
  - The overpressure should be 10-15 Pa
  - The overpressure shall be measured at least once a year
  - The overpressure should permanently supervised by use of a differential meter placed outside the room
  - Windows shall be sealed
  - Doors should be tight-fitting and self-closing
  - …
Example: 4.4.9 Sterilisation... (5)

- **4.4.9.6.2 Monitoring and release**
- It **shall** be monitored and documented that the autoclave has performed a correct process as regards pressure, time, and temperature
- It **shall** be monitored that the sterilised products are dry, intact and uncontaminated
- The products **shall** be cooled before further handling
- A system **shall** be present to allow for distinction between treated and not treated products, cf. EN 554
Example: 4.4.9 Sterilisation... (6)

- 4.4.9.7 Production equipment
- 4.4.9.7.1 Steam autoclave
- The organisation **shall** prescribe requirements for the steam autoclave in accordance with its purpose
- The steam autoclave **shall** be manufactured in compliance with the applicable requirements in EN 285
- The steam autoclave **shall** have a supply at least matching the minimum values of EN 285, Annex B, table B1
- ...
- It **shall** be possible to validate the steam autoclave in compliance with the requirements in EN 554
- ...
- The organisation **shall** determine the extent of routine monitoring and revalidation in compliance with the standards DS 2451-9 and EN 554
6 Educational requirements

- Procedure for training of staff shall be established
- The procedures shall describe work planning, hand hygiene and requirements for working suit and rules of quarantine because of communicable diseases
- Staff participating in the cleaning and sterilisation of products shall have completed the education for CSSD assistants or similar
- Procedures for training of transport personnel shall be established
- Procedures for training of technicians carrying out maintenance of decontamination equipment, e.g. autoclaves, washer disinfectors and ultra sound cleaners shall comply AAMI ST79-D