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EFHSS

DS

Danish Standard for CSSD

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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)

List of content

- 1 Scope
 - Requirements for reprocessing of surgical instruments
- 2 Normative references
 - 52 references to literature
- 3 Definitions
- 4 Requirements
- 4.1 Infection control system
- 4.2 Applicable risk factors
- 4.3 CCP (Critical Control Points)
- 4.4 Critical limits
- 5 Specific requirements for measurement and observation methods [none]
- 6 Specific requirements for responsibilities and education of staff members

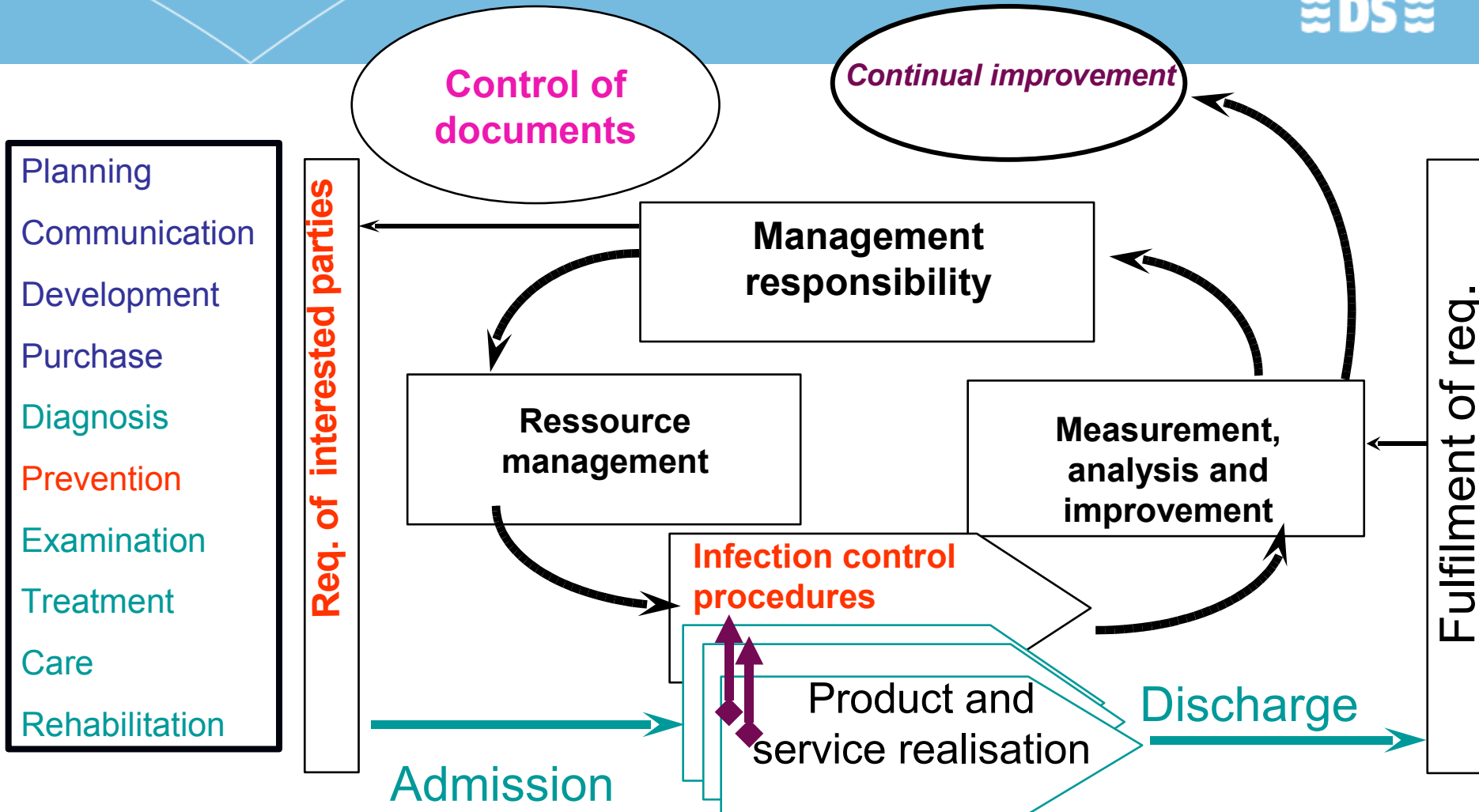
DS 2451-13 clause 4.1

- 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

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Risk assessment

Reduced hazard

Yes



Harm

No

Increased hazard

Hands,
wrists,
forearms

When?

Before clean and after contaminated activities

Procedure

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

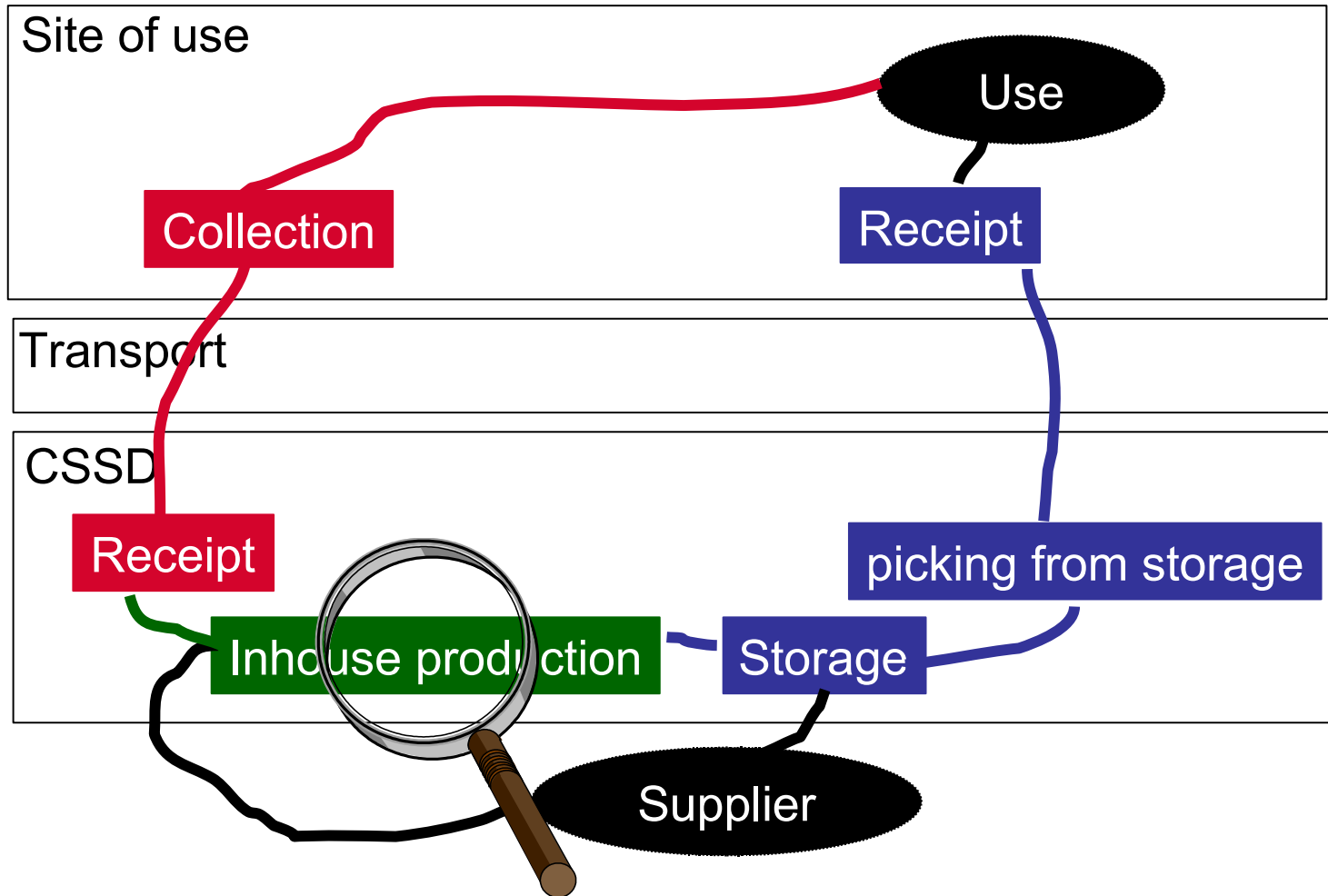
Critical Control Points (CCPs)

- 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

Flowchart



The unclean section of the CSSD

4.4.4

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4.4.6 Receipt of unclean/used products in the CSSD

inhouse production

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

4.4.10

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

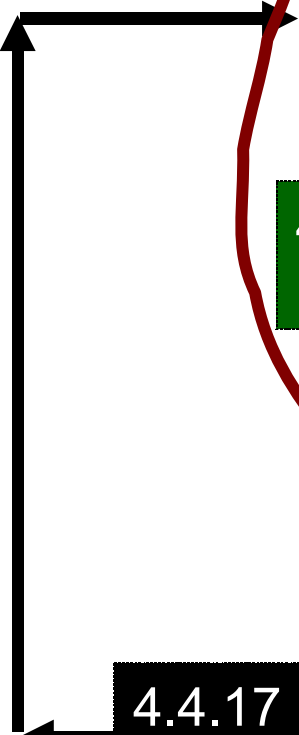
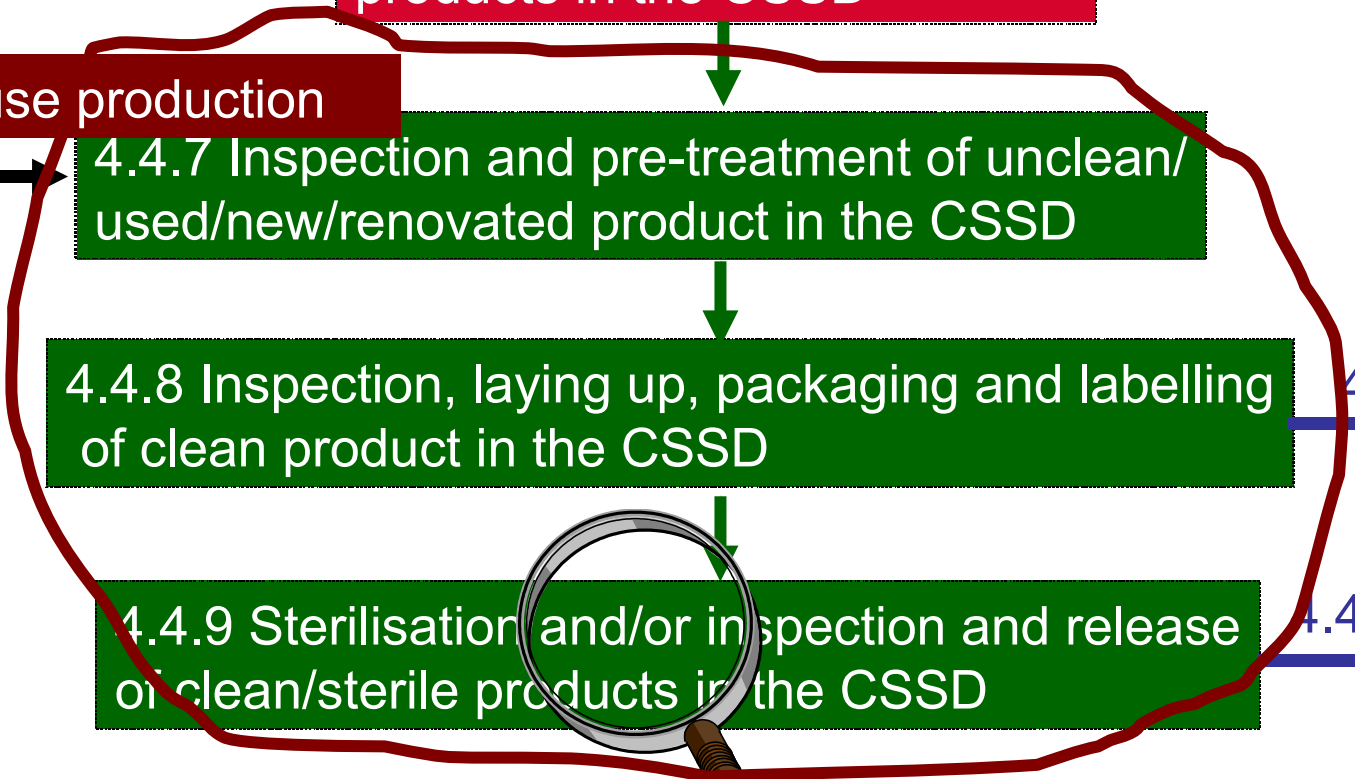
4.4.10

4.4.14

4.4.17 Receipt and inspection of purchased goods and new/renovated products and transport to storages/pre-treatment area

4.4.14

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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

Example: 4.4.9 Sterilisation... (2)

- **4.4.9.2 Working suit**
- dress code should be defined
- a clean working suit shall 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, at de 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