
20th
WORLD
STERILIZATION
CONGRESS
Celebrating Sterilization Science
The Hague - The Netherlands 30 October - 2 November 2019
wfhss
DSMH
20 Years
SVN
50 Years
Welcome
to the 20th World Sterilization Congress

CSD DESIGN 101

CENTRAL STERILIZING DEPARTMENT
GUIDELINE FOR DESIGN, CONSTRUCTION AND STARTUP

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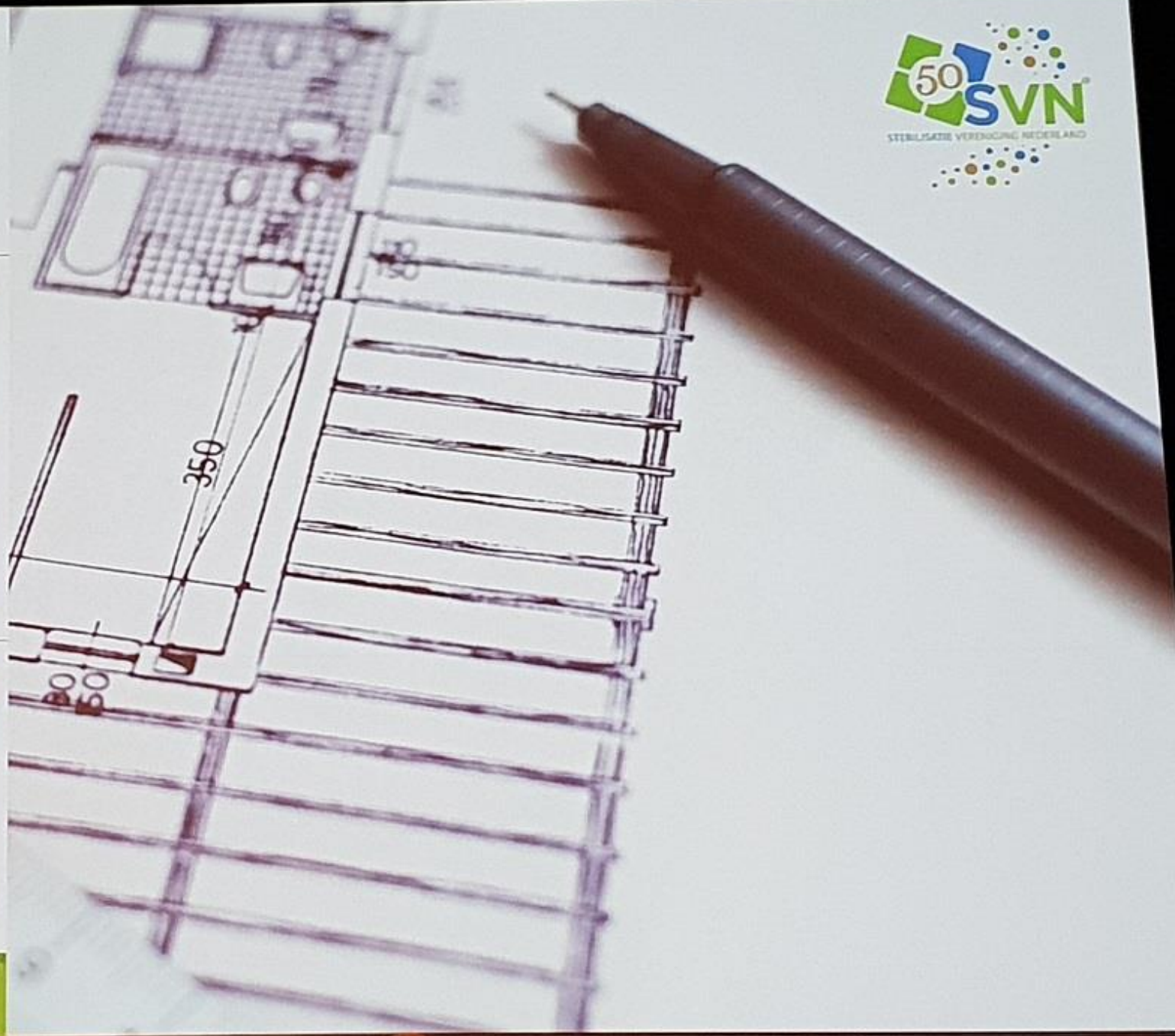

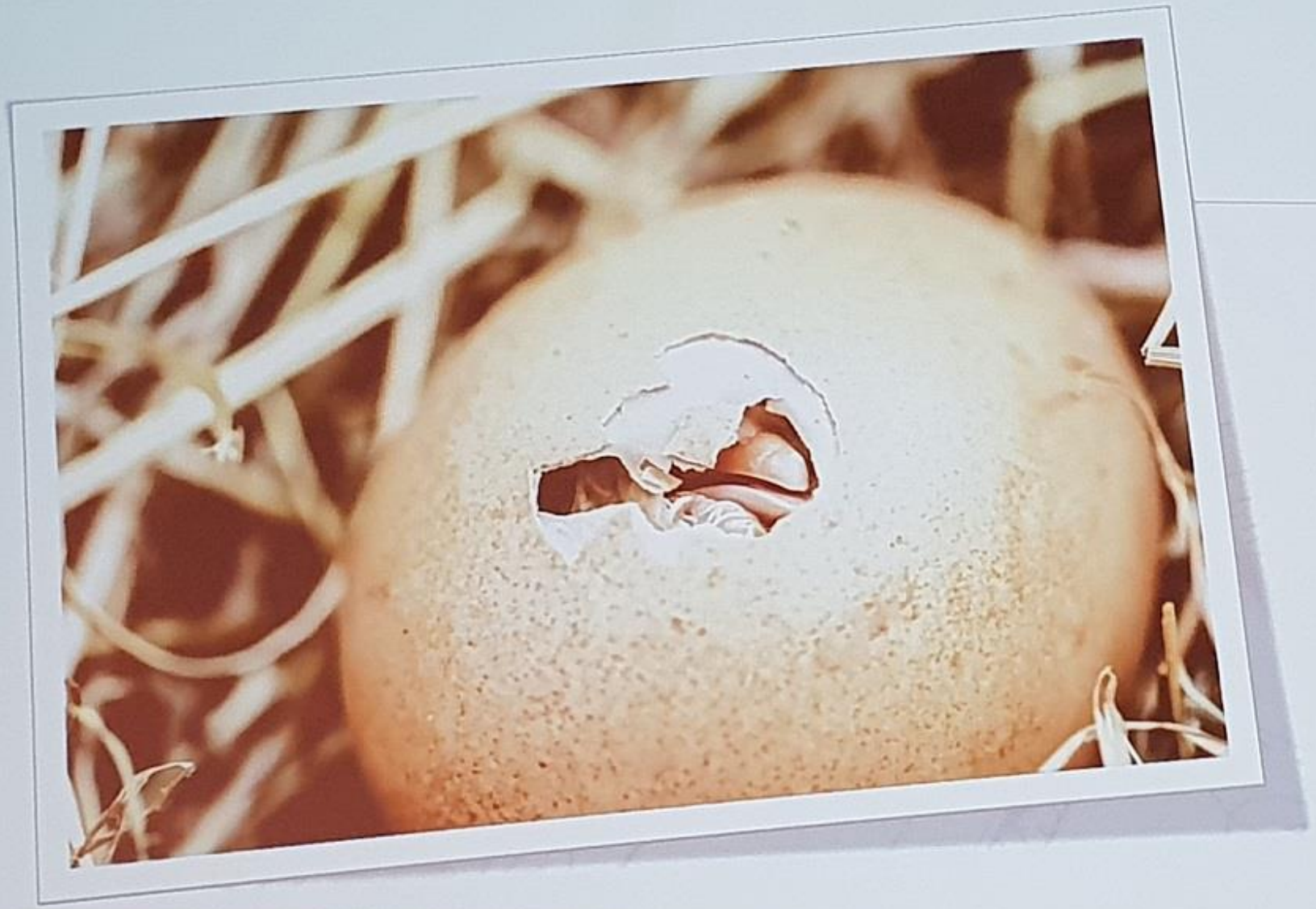

VHIG

SVN

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Why?

Top 10 Patient Safety Concerns
for Healthcare Organizations
2018

Healthcare facilities must ensure that sufficient staff and equipment are available to handle the reprocessing workload; that staff follow current guidelines and manufacturer recommendations; and that the facility's water and environmental filtration system undergoes regular surveillance and maintenance. Additionally, facilities should work to create a team environment for members of the surgical and central sterile processing teams.

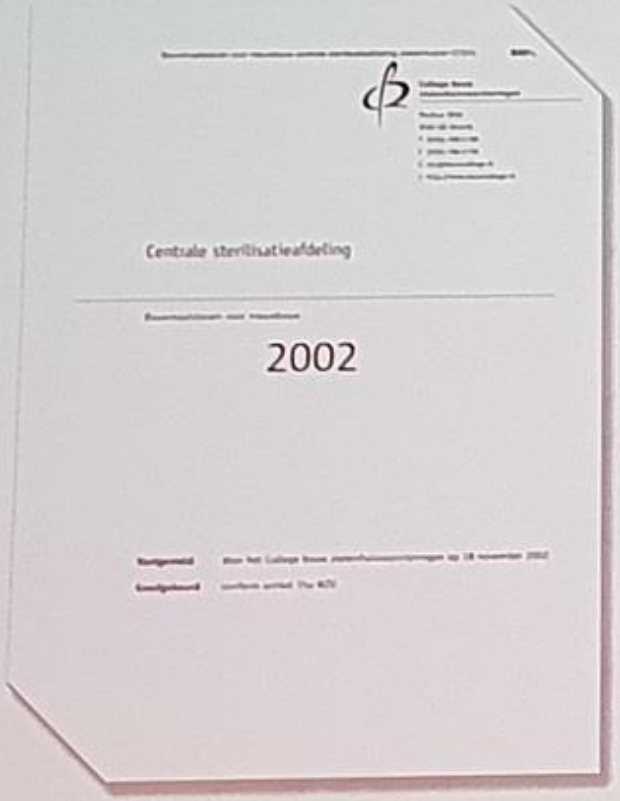
MARCH 2018

ECRI Institute's Top 10 Patient Safety Concerns for 2018

1. Diagnostic errors
2. Opioid safety across the continuum of care
3. Internal care coordination
4. Workarounds
5. Incorporating health IT into patient safety programs
6. Management of behavioral health needs in acute care settings
7. All-hazards emergency preparedness
8. Device cleaning, disinfection, and sterilization
9. Patient engagement and health literacy
10. Leadership engagement in patient safety

#S110

Previous Committee dissolved 2010



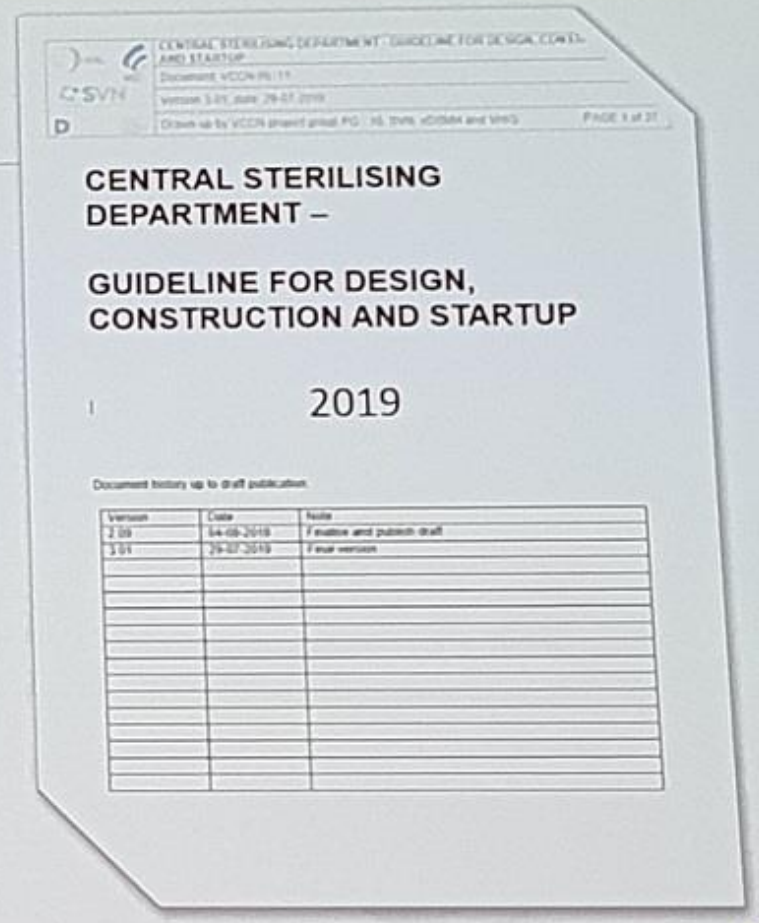
Centrale sterilisatieafdeling

2002

Committee related to the government and in charge of approval of hospital (re)builds

New working group 2017

Consensus document created by national associations related to hospital hygiene and reprocessing of medical devices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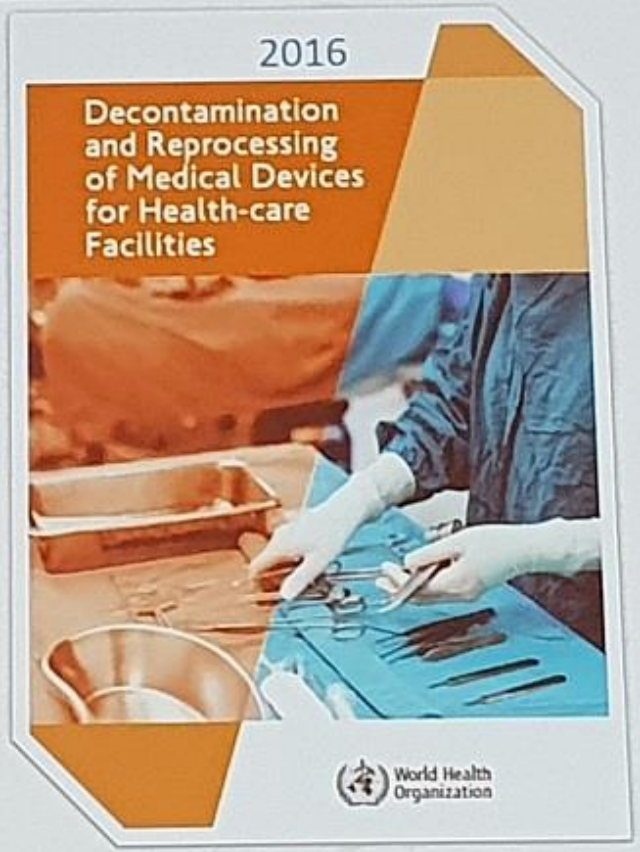
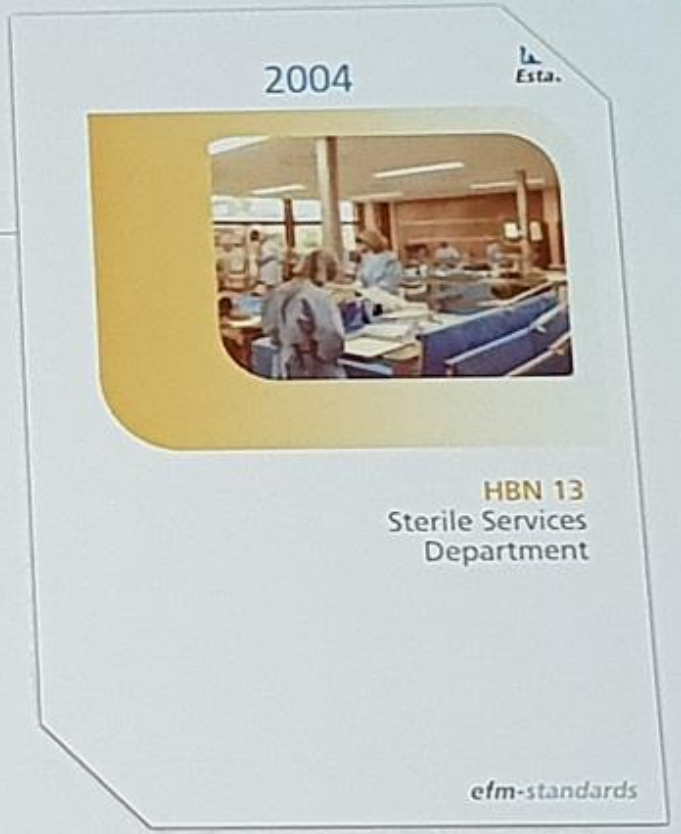
2019

References/Research

- Analysis of scientific research databases for evidence of SSI related to airborne particles.





2002-2019 Personal Full Circle

Afb. 5 Sterilisatoren: de verpakte goederen staan in de pakketteerruimte op beladingswagens klaar om gesteriliseerd te worden.

Previous building code

- Directive
  - Pre calculated values per STU
    - 3 STU per OR
    - Out patient clinic 0,5 STU per suite
  - Pre calculated values in m^2 per STU

Tabel 1 Richtgetallen per functiegroep

Functiegroep:	Richtgetal (in STE)
Operatieafdeling	3,0 per werkuur per operatiekamer * * inclusief poliklinische ingrepen
Poliklinische behandeling	0,5 per werkuur per behandelkamer *
Klinische verpleging	0,05 per bed per dag
Dagverpleging	0,25 per bed per dag

Tabel 2 Relatie jaarproductie en ruimtebehoefte (in m²)

Jaarproductie (in STE):	26.000 STE	52.000 STE	78.000 STE
Nuttige oppervlakte productieruimten	160	280	410
Nuttige oppervlakte kantoor- en vergaderfuncties	45	65	85
Nuttige oppervlakte centraal steriel magazijn en uitpakruimte	PM	PM	PM
Totale nuttige oppervlakte	205 + PM	345 + PM	495 + PM
Totale bruto vloeroppervlakte, afgerond (bruto/nuttig-factor 1,35)	280 + PM	470 + PM	665 + PM

For whom

3.1 Scope and objective of the Guideline

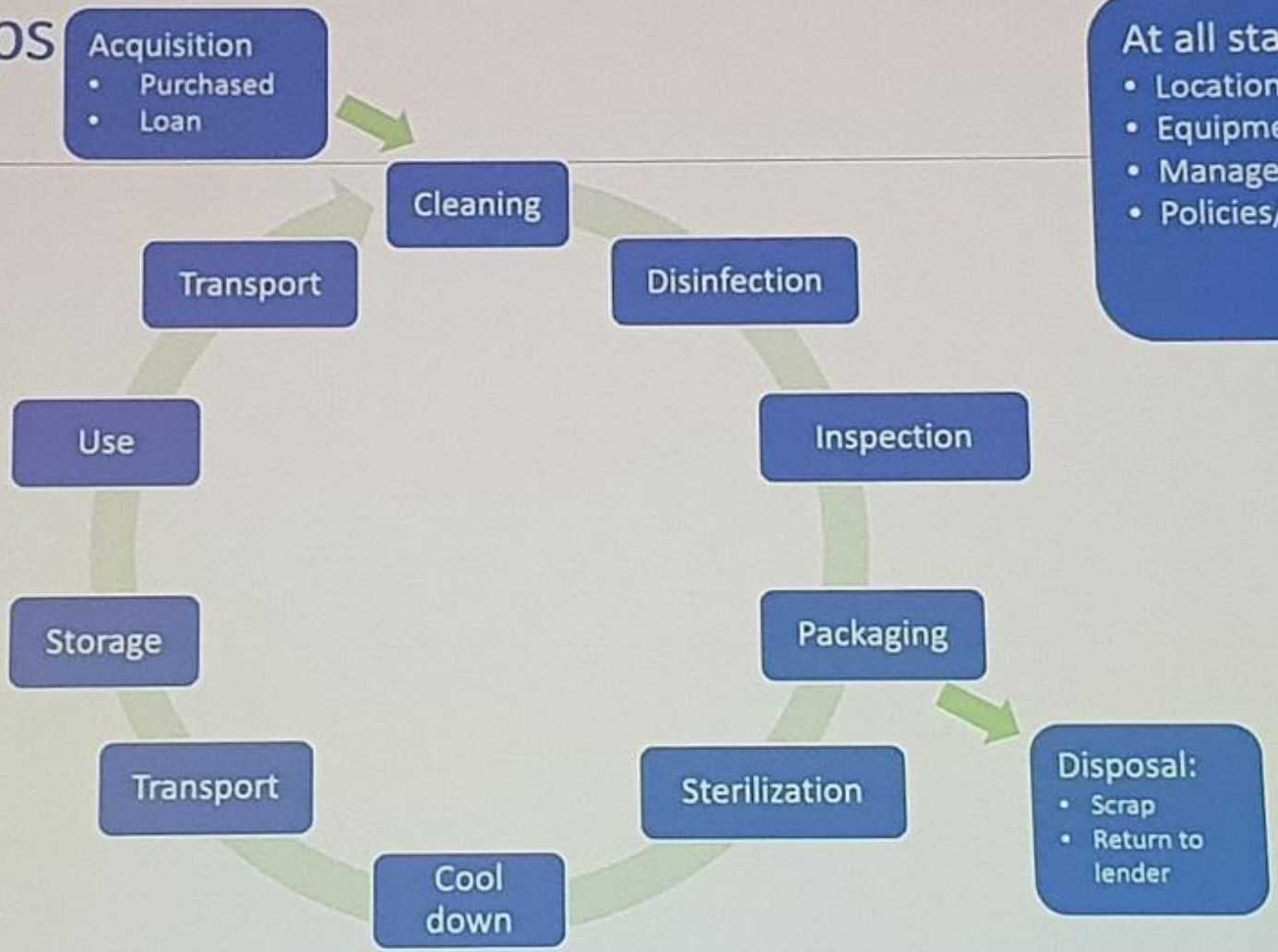
This Guideline serves as a tool for anyone involved in defining requirements, designing, building and determining the layout and maintenance of the sterilising department.

This Guideline focuses on Central Sterilising Departments (CSDs)

- in hospitals, independent treatment centres and organisations that sterilise reusable medical devices for these parties,
- where reusable medical devices for human use are cleaned, checked, packed, sterilized, released and stored.

This guideline does not contain any specific organisational models and/or process requirements. For process requirements, please refer to the relevant standards and guidelines.

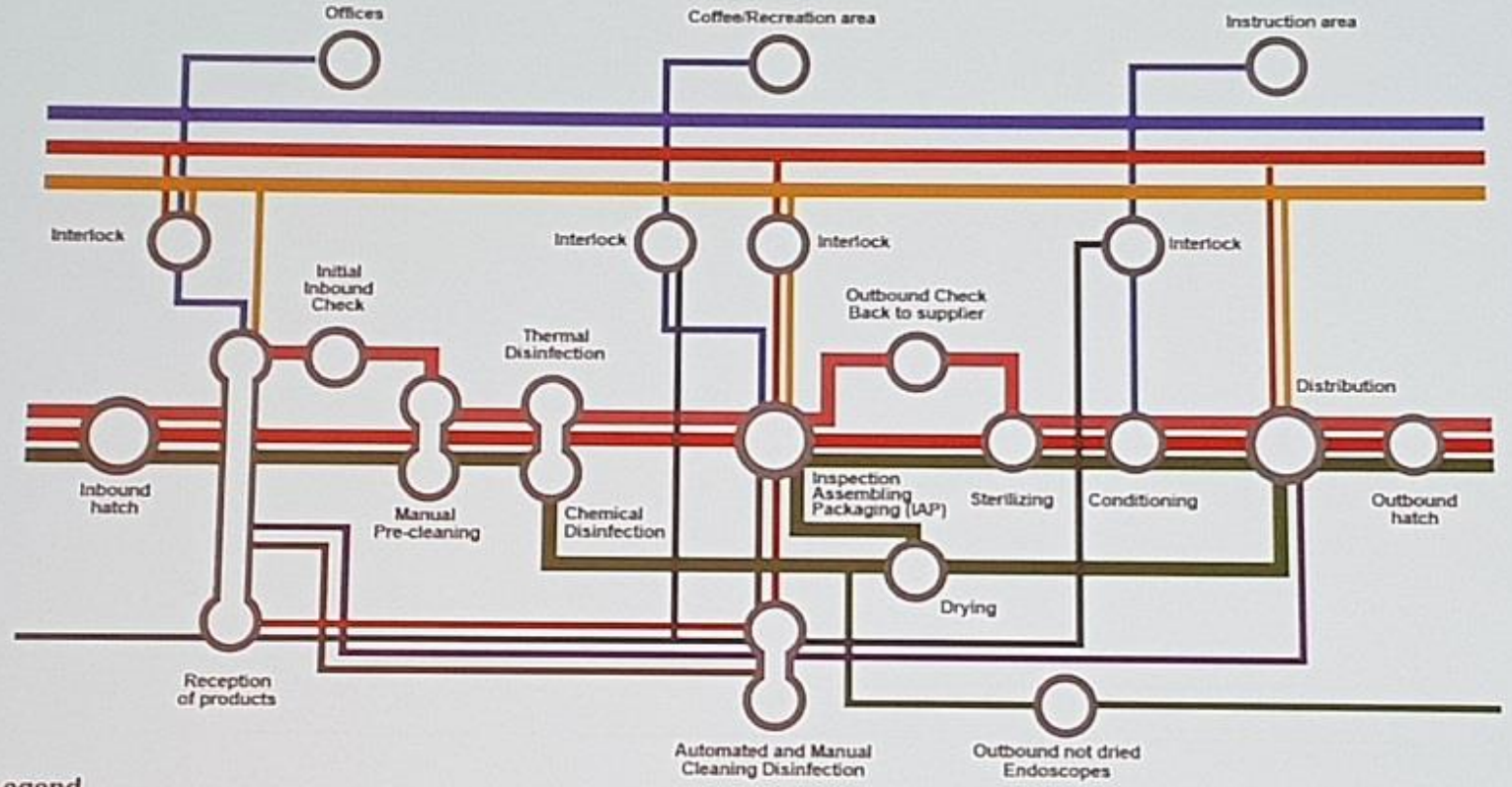
Process steps



CSSD Product range

- Surgical Instruments
- Staff
- Loaner Instruments
- Flexible Endoscopes
- Sterilization Baskets & Containers
- Transport Trolleys & Boxes
- Theatre Shoes
- Consumables
- Waste

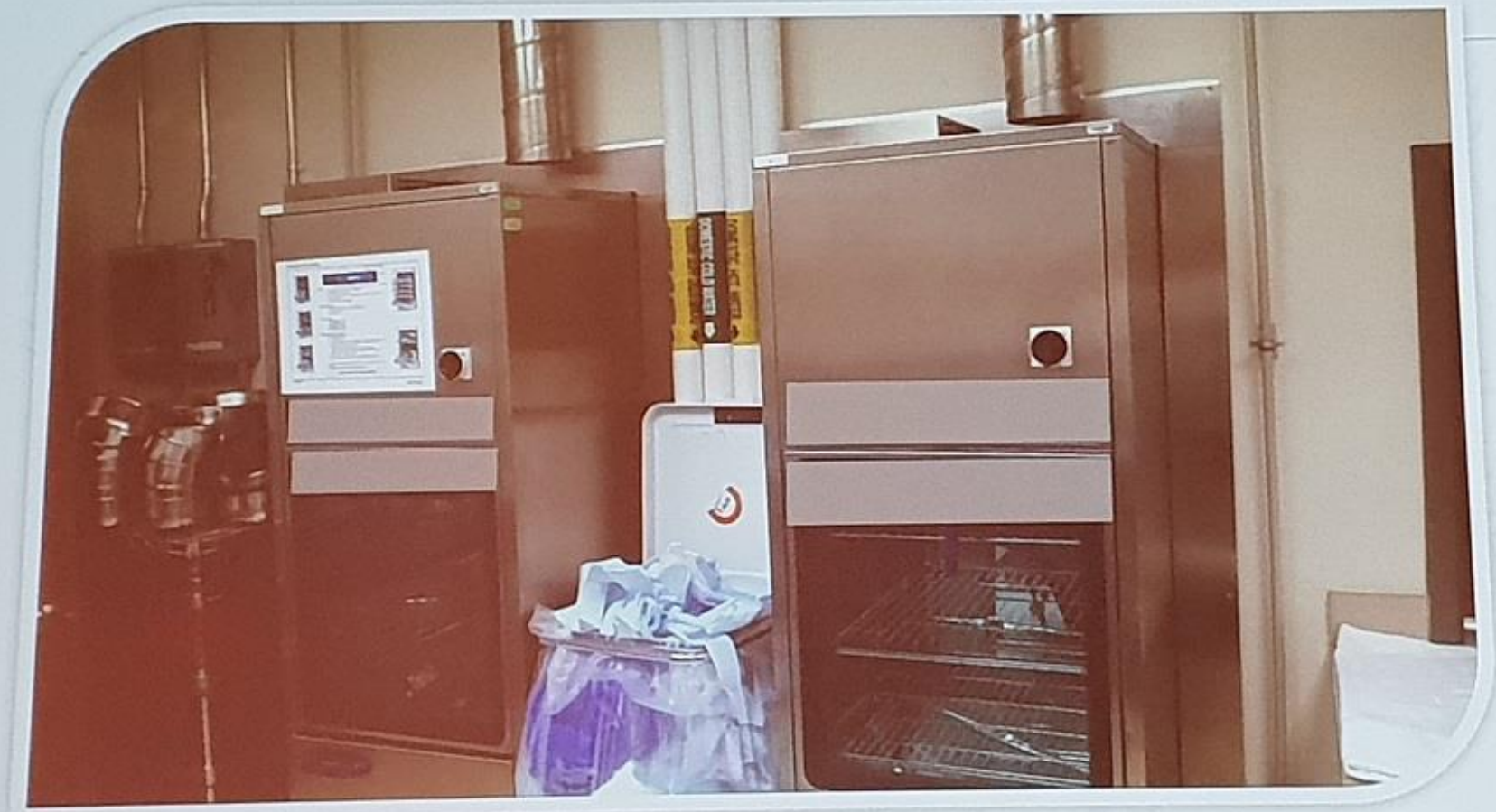
CSSD Workflow



Legend

- Single activity
- Combined activities
- Surgical Instruments
- Staff
- Loaner Instruments
- Flexible Endoscopes
- Sterilization Baskets & Containers
- Transport Trolleys & Boxes
- Theatre Shoes
- Consumables
- Waste

A matter of perspective and local standards



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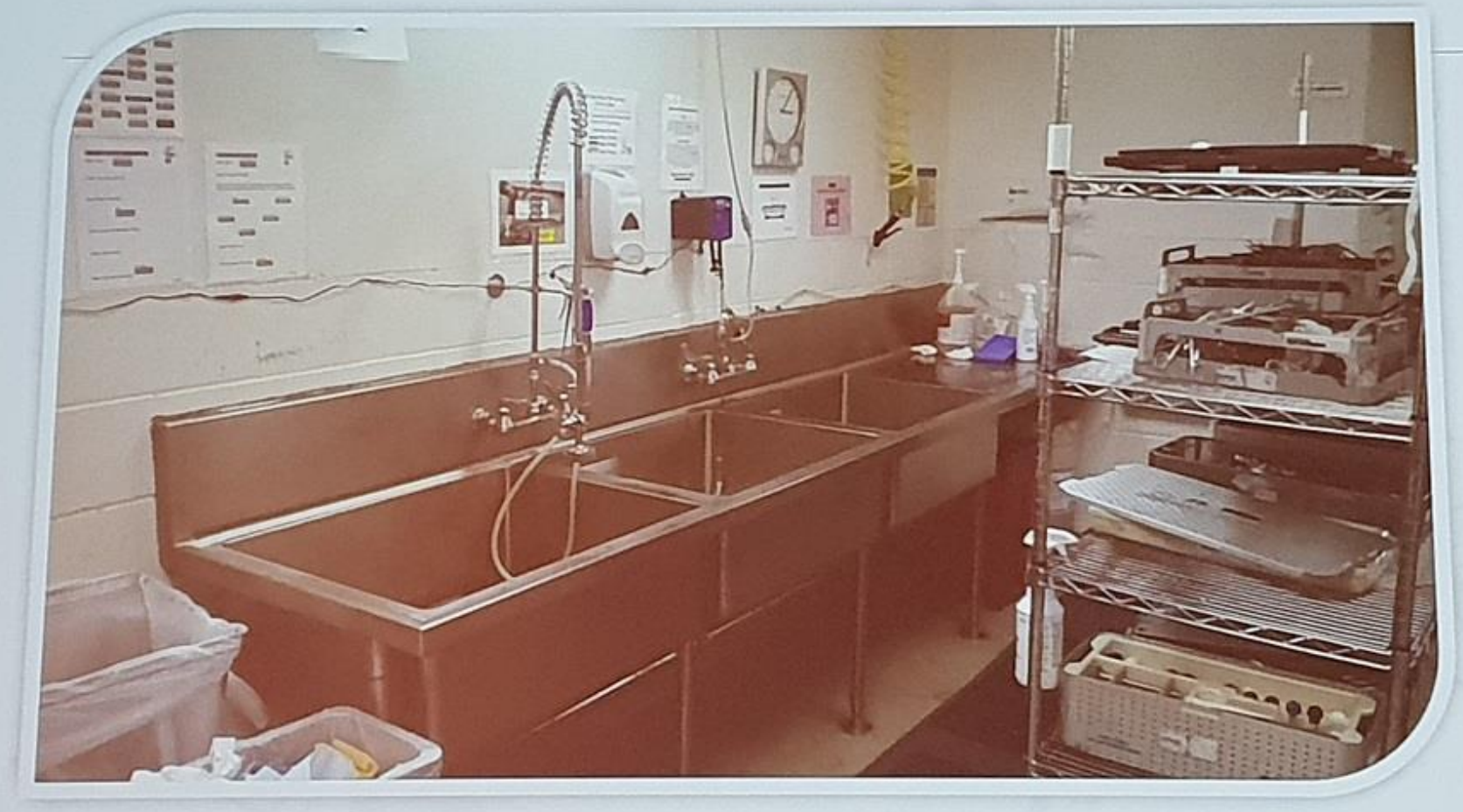

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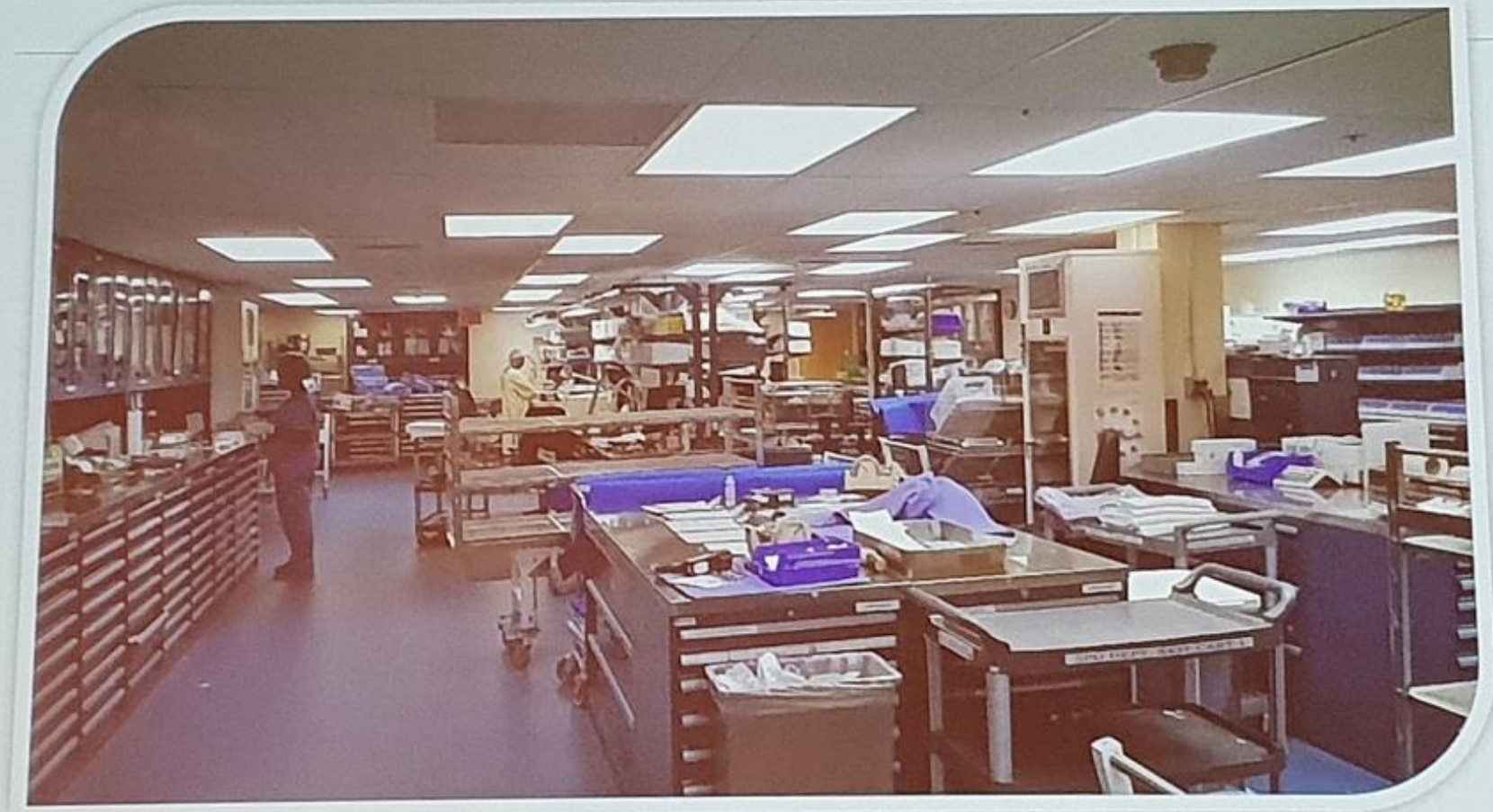
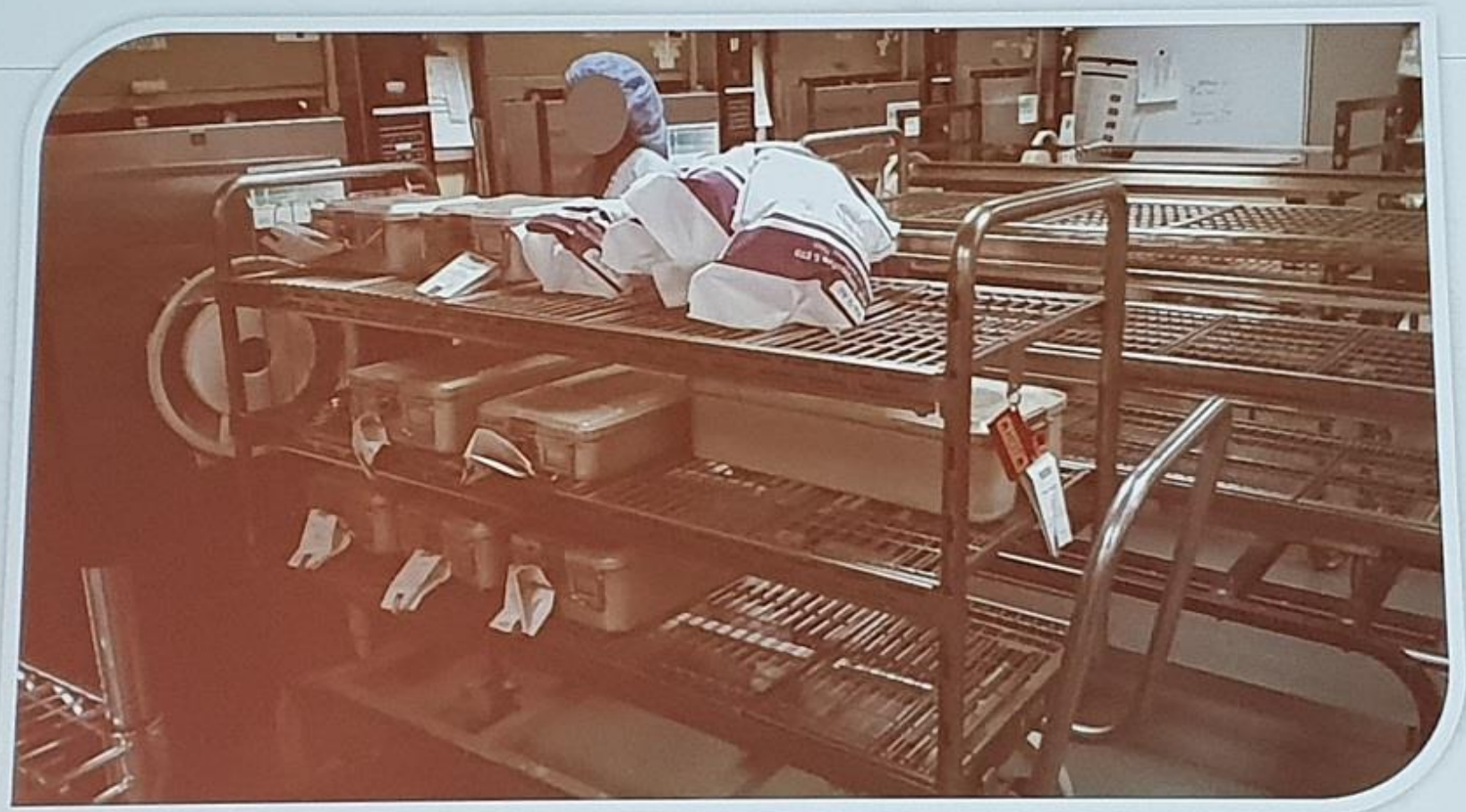


A matter of perspective and local standards



A matter of perspective and local standards

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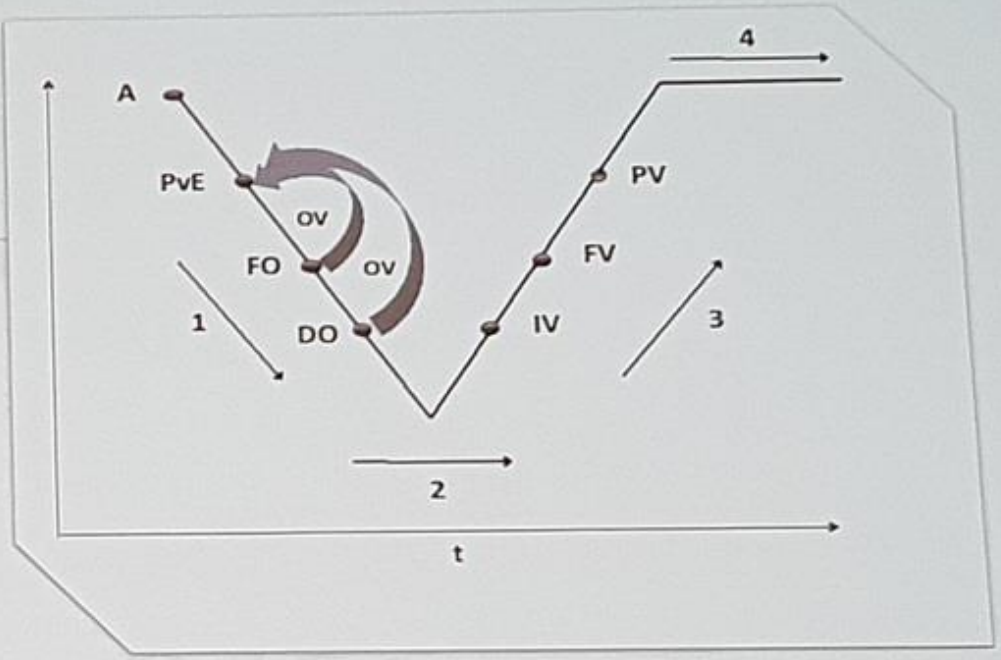
Design process



1	Design phase	FD	Functional Design (FO)
2	Realisation phase	DD	Detailed Design (DO)
3	Verification phase	DV	Design Verification (OV)
4	Maintenance phase	IV	Installation Verification
A	Analysis	FV	Functional Verification
LoR	List of Requirements	PV	Performance Verification

Design process, verification process, maintenance and management

Layout of activities/rooms by zone

Dirty	Clean	Public
• Reception room for dirty medical devices • Cleaning and disinfection room • Decontamination room for transport equipment, baskets • Service area for cleaning	• Room for disinfected medical devices • IAP room • Cool down/discharge room • Storage and transport room for sterilised medical devices • Service area for cleaning	• Staff facilities, break room, administrative office • Service rooms for cleaning and waste • Room for the reception and storage of consumables • Room for transport materials (e.g. trolleys and carts)

Key requirements and recommendations

- Map each process steps (metro map). When designing an CSD, future developments must also be taken into account. This does not just include scaled-up production, but also different process formats resulting from a shift to processing medical devices of a different nature.
- The department must be strictly and physically compartmentalised into several zones, in which processes can take place that require different levels of cleanliness. In addition, there must be a single, unidirectional air flow - leading from clean to dirty - throughout the entire department.
- Automatic thermal disinfectors should have a double-door layout and must be installed in the wall separating dirty and clean areas.
- Sterilizers should have a double-door layout and must be installed in the wall between the IAP room and the unloading/cool down area.

Key requirements and recommendations

- The IAP room, evaporation/discharge area must comply with ISO-7 classification “at rest” for particle sizes equal to or larger than 0.5µm, as well as featuring a unidirectional air flow from clean to dirty.

- The IAP room, the evaporation/discharge area must comply with a recovery time of no more than 20 minutes with a 100-fold concentration reduction of 0.5µm particles, in accordance with NEN-EN-ISO 14644-3.

- The requirements for the IAP room (ISO 7) are based on the prevention of contamination (sedimentation) of the instruments with particles in the period between cleaning and packaging. Literature shows that sterile particles on instruments can lead to Toxic Anterior Segment Syndrome (TASS), especially in ophthalmic procedures. It is therefore advisable to keep the time between the instruments are cleaned and packed as short as possible.

IAP room (Inspection, Assembly, Packing)

- The IAP room serves as a place to inspect and re-assemble cleaned medical devices, before subjecting them to functional checks and tests, if required, and packing them for the following sterilization process.
- Trolleys and other rolling equipment that are used outside the clean zone may not pass through the locks.
- The IAP room must feature an air lock for clean packaging materials and all other tools and devices used in the IAP room.
- The IAP room must feature all connections required for checking and testing equipment.
- This room may not feature any taps or drains.
- The logistics lock must preferably feature a hand disinfection system.

Architectural finishing

- Floor, wall and ceiling finishes must be smooth, seamless and closed.
- The ceiling must be of cleanroom quality and comply with NEN EN ISO 1644-4:2001, E2.1.2.
- The room may not have facade openings that can be opened.
- It must be possible to clean and disinfect the floor, ceiling and walls with agents permitted in hospitals.
- Walls in storage and production rooms/spaces and other spaces accessible to heavily loaded carts must be resistant to or protected against impact. For this purpose, the following measures can be taken, among others: bumpers, risers, guide rails.
- Walls must be constructed in such a way as to prevent condensation in corners or construction beams.
- Ceilings in cleaning, packing and sterilizing rooms/spaces must be able to withstand the high humidity levels
- For doors that are opened frequently, sliding doors are preferred on recovery time and the required air flow.
- All other doors in a CSD must close automatically (e.g. by installing door closers).

Risk analysis & Reclassification

Risk analysis is a systematic process of hazard identification, as well as the analysis and evaluation of risks associated with exposure to those hazards.

A risk analysis is performed in order to:

- Develop a monitoring plan by determining factors that may affect the ability to maintain the specified air purity levels by carrying out particle concentration analyses in the cleanroom or clean zone and establishing
- Monitoring requirements to provide proof of performance.

Reclassification

- The CSD must be reclassified on a regular basis. This is done in accordance with the tests and testing plan described in section 9.

- ISO 14644-1 stipulates that CSDs must be reclassified every year. The frequency of reclassification can be reduced based on the outcome of the risk analysis, the nature of the monitoring system and data that consistently fall within acceptance limits or levels defined in the monitoring plan.

Cleaning during realization phase

- Cleaning is essential during this phase. VCCN Guideline 4, Surface Cleanliness and NEN-EN-ISO 14644-5 describes the general regulations and recommendations for cleaning work related to the construction, delivery, commissioning and operation of dust and germ-free rooms. This guideline specifies 10 distinct cleaning phases. These phases should also be implemented when building a CSD.

- Work related to renovation, construction, maintenance and tests can also be detrimental to the integrity of the existing production environment. These types of activities may never disrupt any operational CSD. Risk analysis is a systematic process of hazard identification, as well as the analysis and evaluation of risks associated with exposure to those hazards.

- Solutions can be introduced in the basic design to mitigate the effects of these activities in the future.

Testing Plan / Commissioning Plan

Mandatory tests:	Requirement:	Complies with standard/guideline:
Particle measurements	ISO 7 at rest, 0.5 µm, 5.0 µm	NEN-EN-ISO 14644-1
Recovery time measurements	≤20 min with factor 0.01	NEN-EN-ISO 14644-3
Pressure hierarchy	In accordance with Appendix 1	NEN-EN-ISO 14644-3
Filter leak tests	n=0	NEN-EN-ISO 14644-3
Air quantities/ Circulation rates	Follows from LoR & Design	NEN-EN 12599

Optional tests:	Requirement:	Complies with standard/guideline:
Light intensity measurements		In consultation
Sound measurements		In consultation
Microbiological measurements		NEN-EN-ISO 14698-1
Temperature/humidity measurements		NEN-EN-ISO 14644-3
Airflow profile	In accordance with Appendix 1	NEN-EN-ISO 14644-3
Air permeability test	E.g. Class L1, from 10 Pa to 50 Pa, positive & negative pressure	VCCN Guideline 10


Sterilization Baskets & Containers
Transport Trolleys & Boxes
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Surgical Instruments
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SVN


Theatre Shoes
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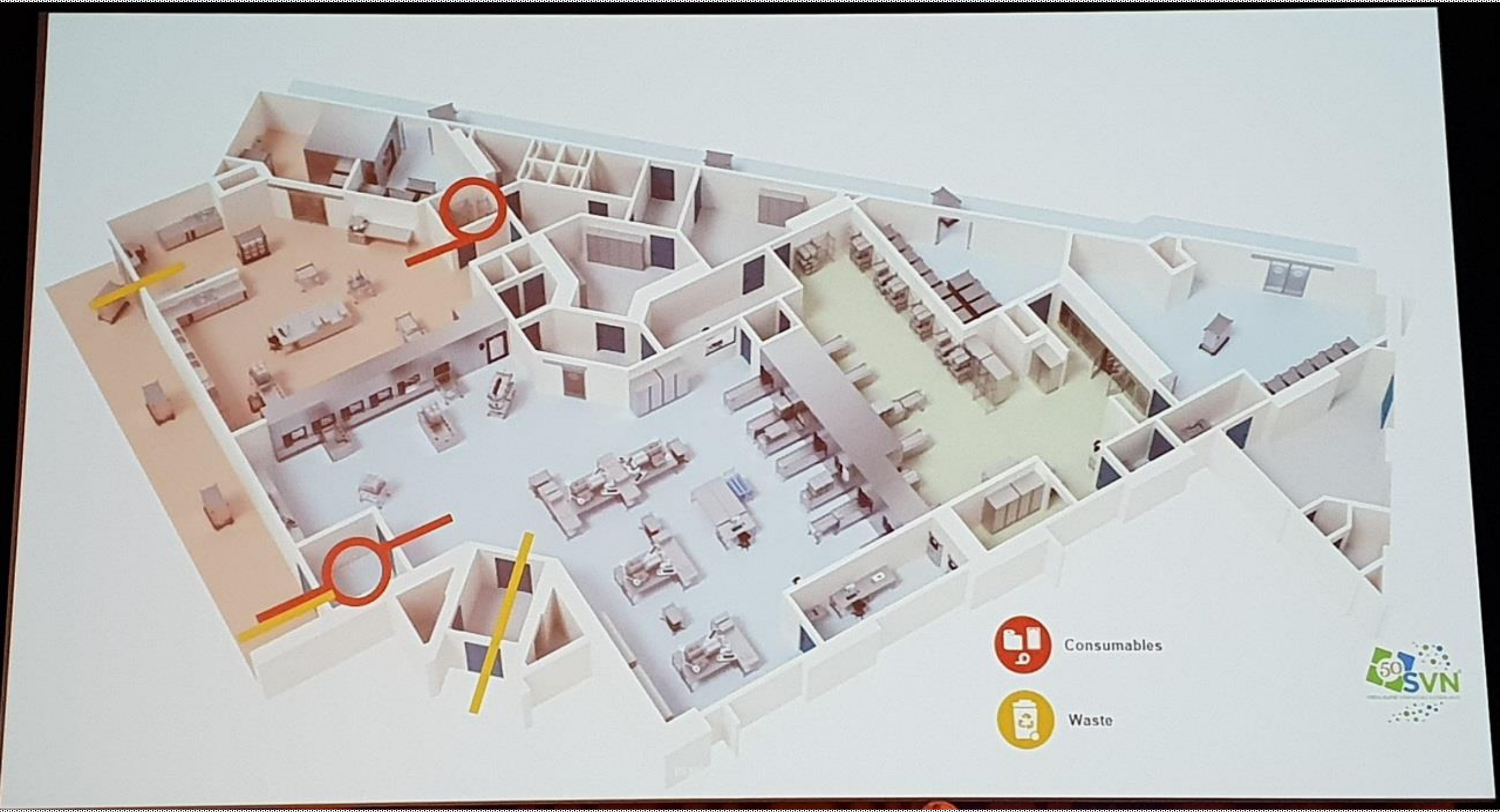
Consumables
Waste
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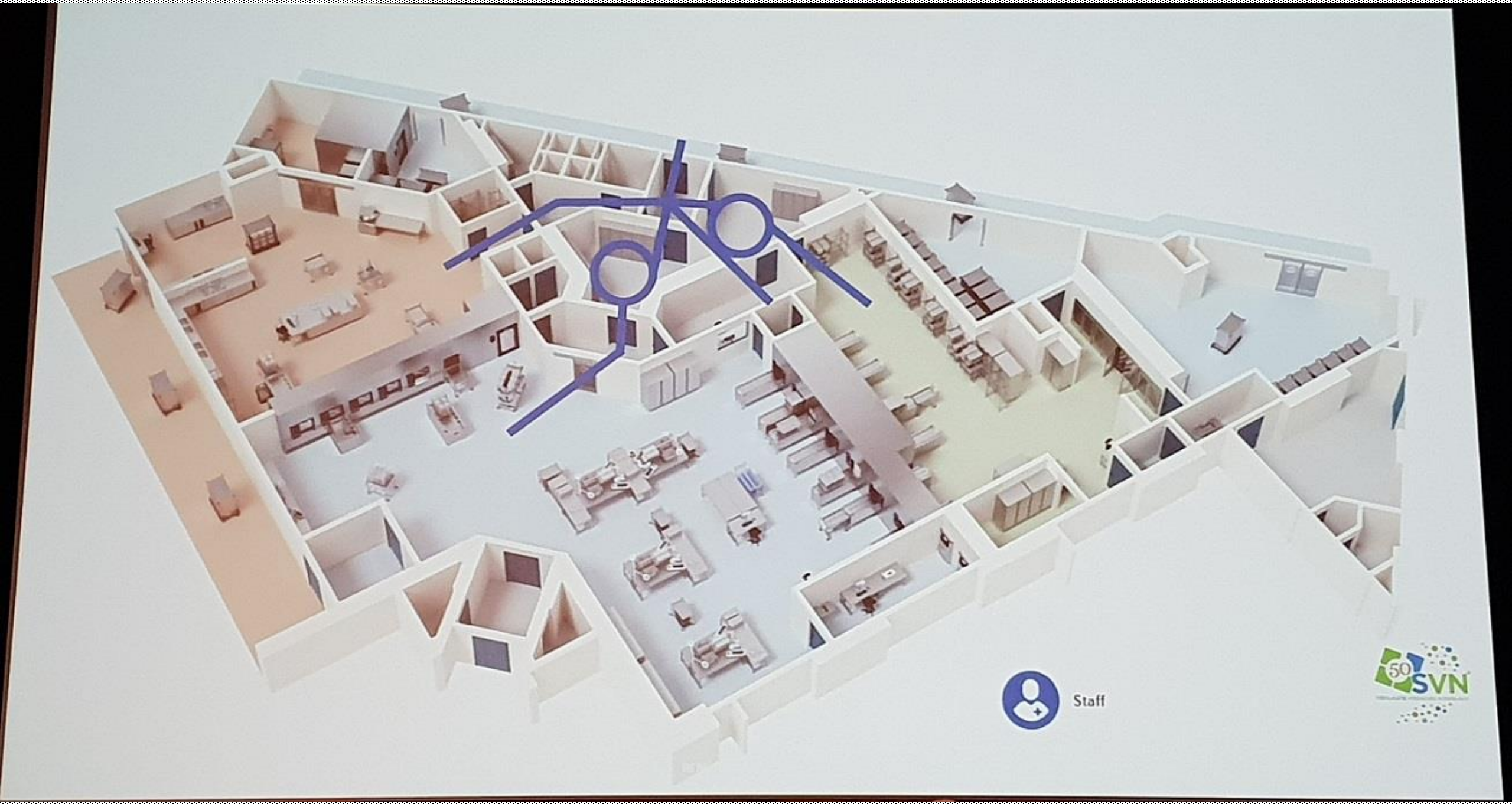
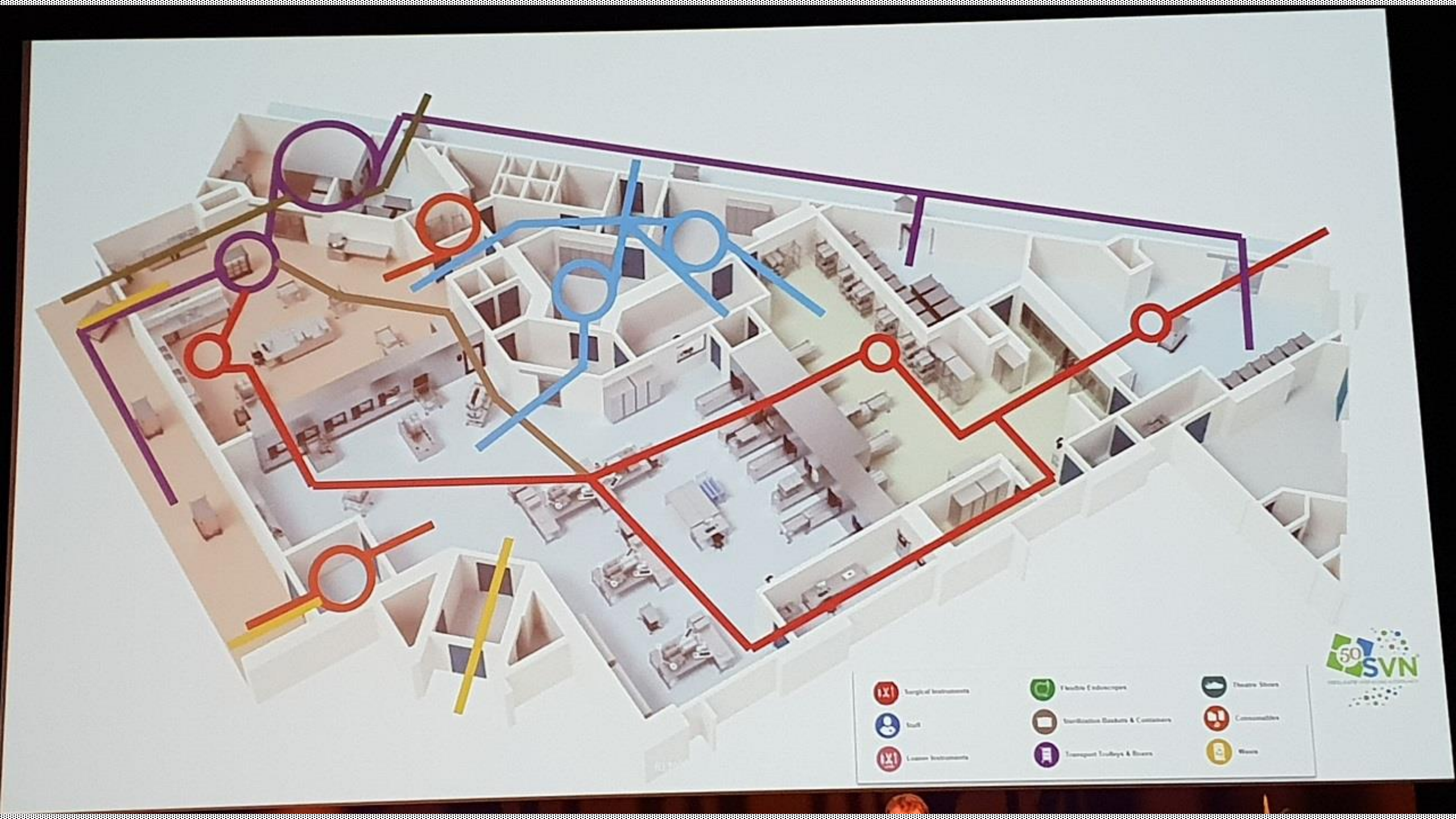

Staff


Surgical Instruments
Flexible Endoscopes
Theatre Shoes
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Sterilisation Baskets & Containers
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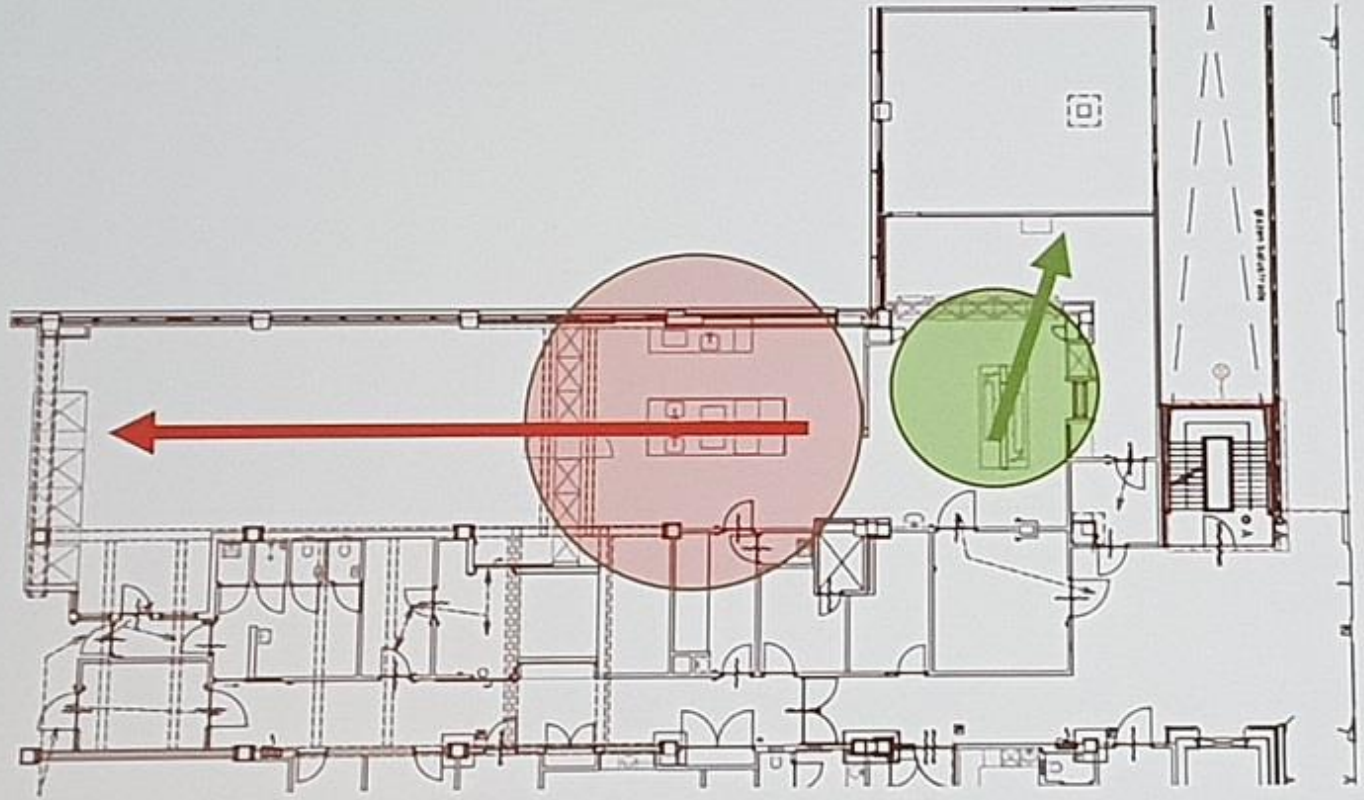
Loaner Instruments
Transport Trolleys & Boxes
Waste
50
SVN

Combining endoscopy



Surgical Instruments

Flexible Endoscopes

Conclusions

- No evidence based standards available
  - Airborne particles
  - Cleanliness of the work spaces
  - Air tightness of equipment and areas
- More research need from the work field needed

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- This building code (and others) are expert opinions. Is a consensus document
  - Based upon (inter) national standards

Conclusions

- No evidence based standards available
  - Airborne particles
  - Cleanliness of the work spaces
  - Air tightness of equipment and areas
- More research need from the work field needed
- This building code (and others) are expert opinions. Is a consensus document
  - Based upon (inter) national standards
- This building code supplies qualitative but no quantitative guidance
  - No capacity calculations on equipment or m^2
  - Provides detailed description of flows and requirements for layout, functional and spatial conditions

Thank you for you attention

www.vccn.nl/rl-11-centrale-sterilisatie-afdeling NL/EN