



# Loan instruments

Neither a borrower nor a lender be  
For loan oft loses both itself and friend

William Shakespeare  
Hamlet 1600



# Sharing information

- Problem Definition
- National standard
  - Published December 1997
- Layout and implementation the the standard
- Present status of the standard
- Conclusion

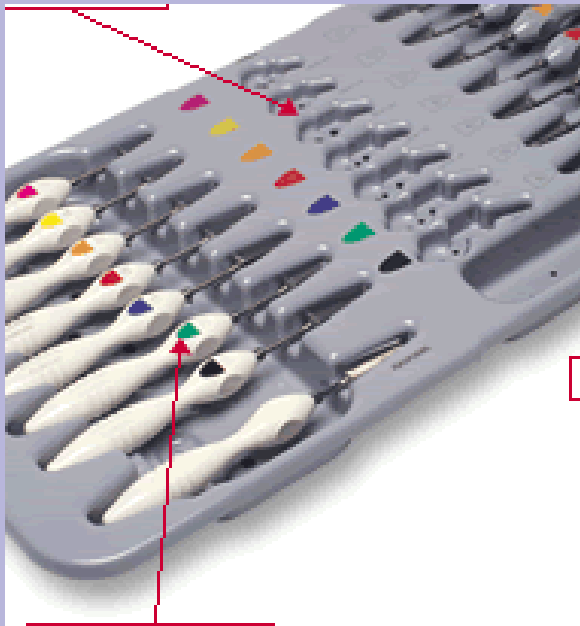


# Problem definition

- Validation of the reprocessing within the CSSD quality system
- Risk of CJD contamination
- Surprise attack
  - Reprocessing within an hour
  - Unknown instruments
- No reprocessing information provided
  - Preparation, cleaning, disinfection
  - Inspection, maintenance and testing
  - Packaging and sterilization
- Mostly in CSSD unfriendly trays

# Trays

problem



Much better



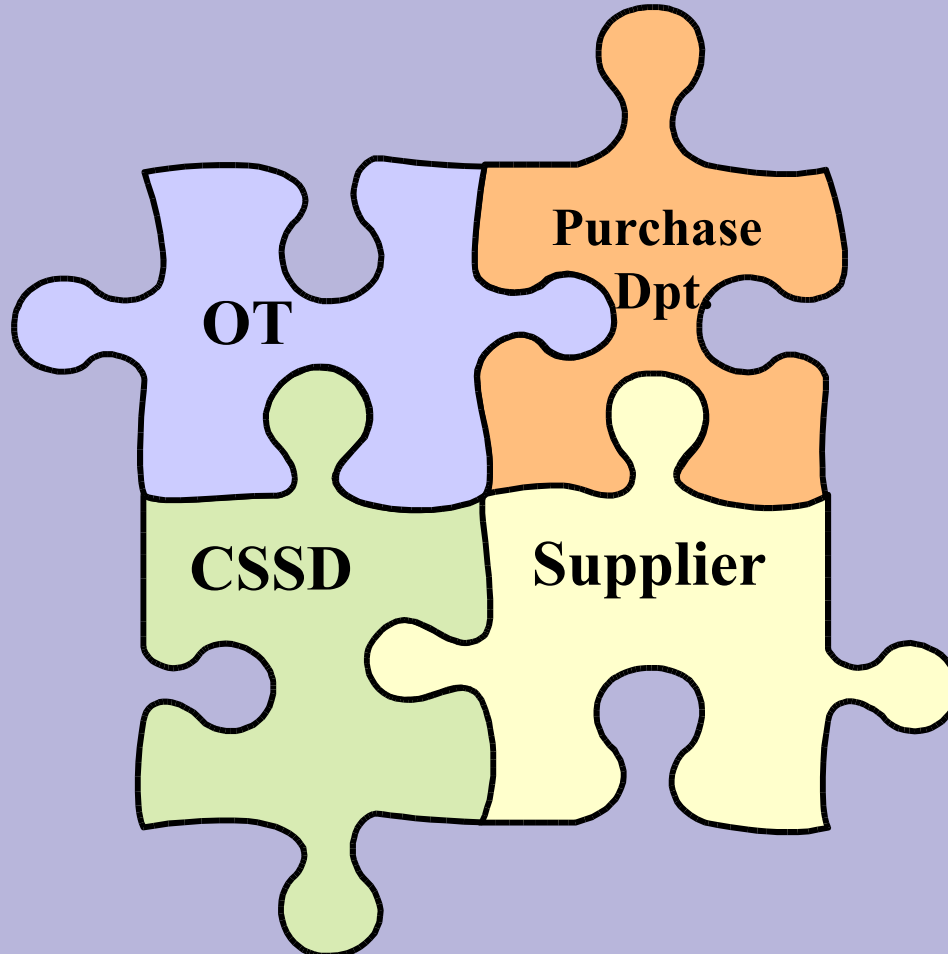
# Just for fun!





# National standard

- When?





# National standard

- Why???
  - Every hospital has the same problems
  - Every supplier has the same problems
  - Use versus reprocessing
  - Responsibilities of hospital and supplier must be clear



## National standard

- Who?
  - Operating theatre staff
  - Hospital purchase department
  - Manufacturer/supplier
  - CSSD
- Dutch Orthopaedic Trade Society (DOTS)
- Dutch Central Sterilization Club



# Normative references

- Besluit gesteriliseerde medische hulpmiddelen in ziekenhuizen (1983)
  - Dutch legislation on sterilization in hospitals
- Medical Device Directive
  - Essential requirements §13.6h
- EN 285 and EN 554
- prEN ISO 15883 part 1
  - 8 tests of cleaning efficacy
- prEN ISO 17664
  - Information to be provided by the manufacturer for reprocessing of resterilizable medical devices



# Responsibilities

- Supplier is responsible for the instruments and the provided information
- Hospital is responsible for the reprocessing
  - Manager CSSD and Sterilization Quality Manager
  - Based on the information provided by the supplier and the interpretation of that data.
- After reprocessing the hospital must provide the supplier with a declaration of decontamination



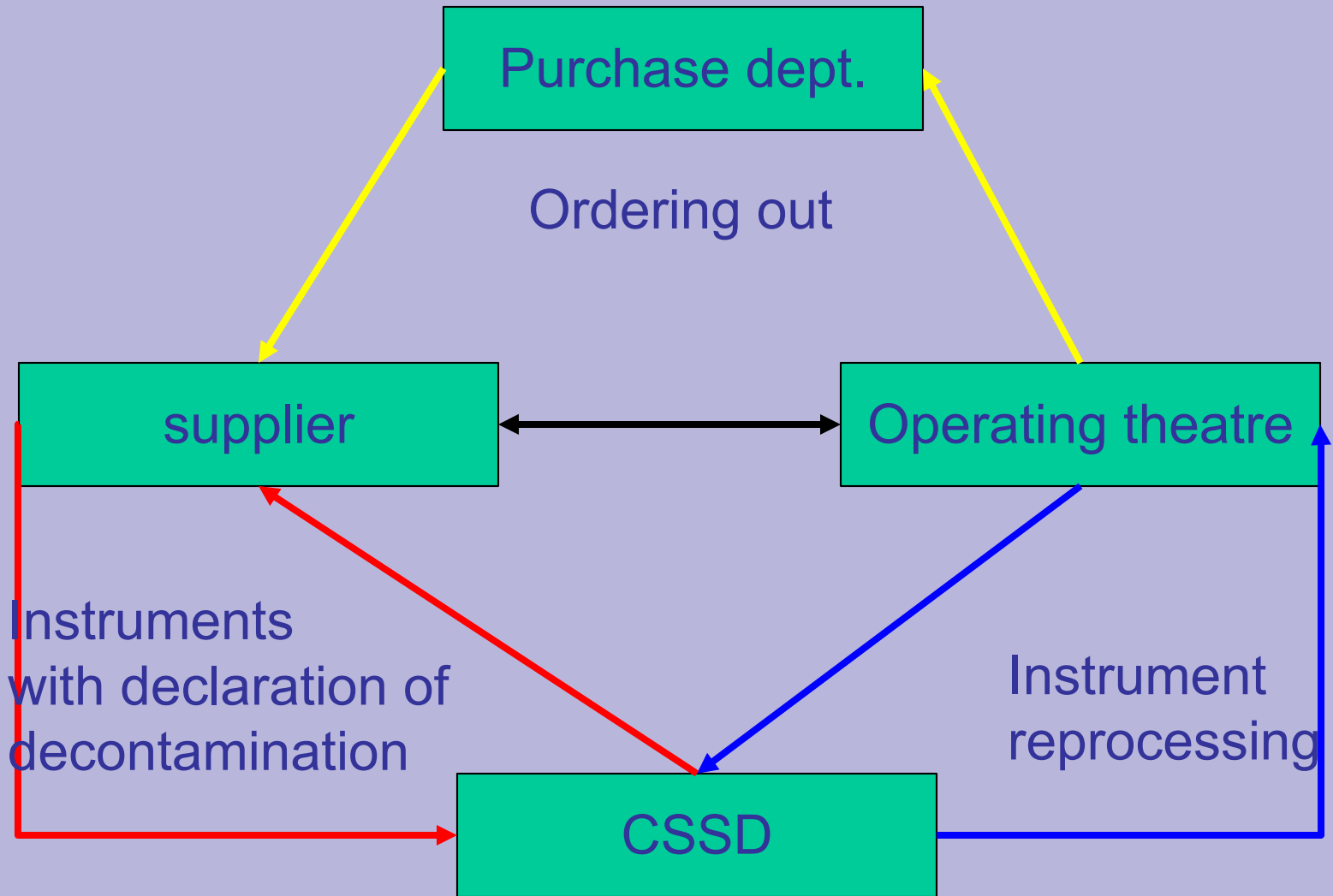
## Layout of the standard

- Published December 1997
- Supplier informs the CSSD
  - Completed registration form
  - Declaration of decontamination
  - Tray list
  - Cleaning, disinfecting and sterilization protocol
  - Maintenance instructions
- In case of new instruments the CSSD needs 2 workdays to process the data and to instruct the staff



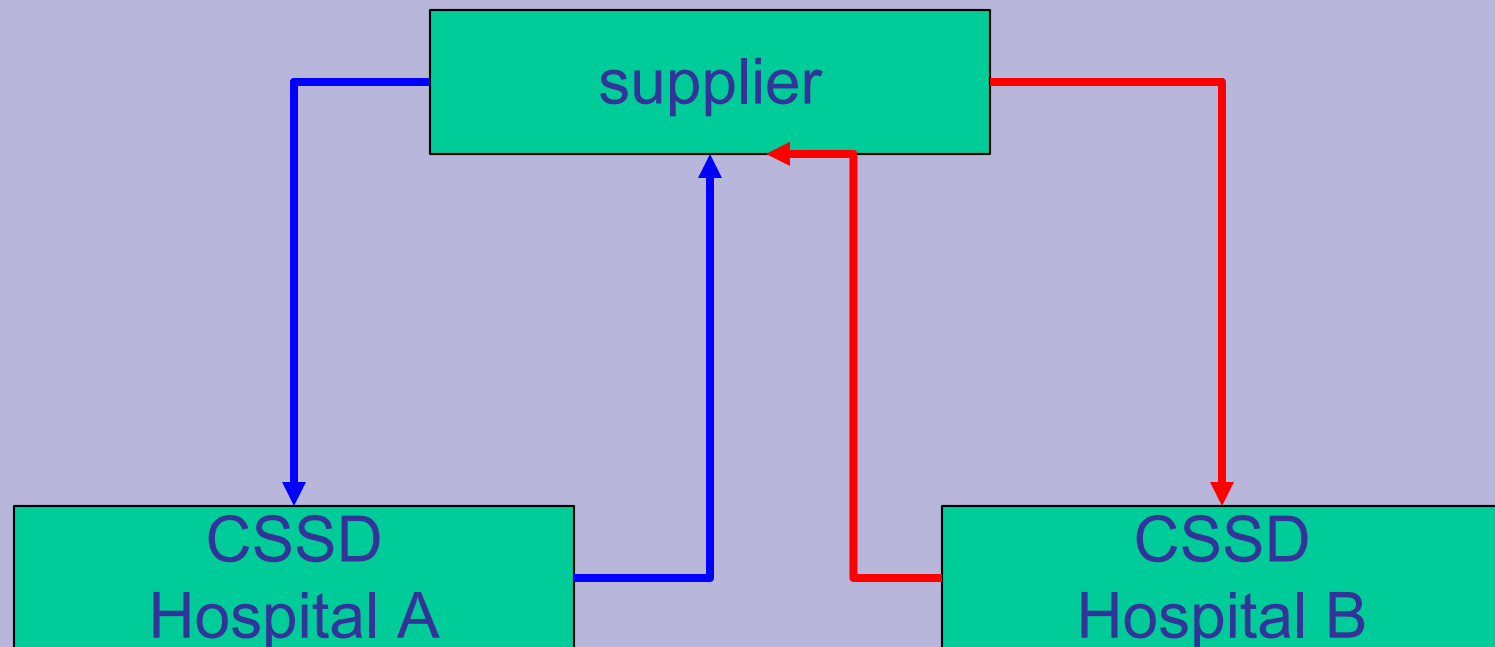
## Layout of the standard

- Delivering the instruments at the CSSD
  - Transportation in closed transport box
  - Supplier issues a declaration of decontamination
    - Prions/CJD protocol
    - Cleaning, disinfection and sterilized (not sterile)
- CSSD needs 1 workday for reprocessing before the procedure
- CSSD needs 1 workday for after the procedure





# Declaration of decontamination





# Record keeping

- The hospital must keep a dossier with all relevant data of the loan instruments
  - Registration form
  - Declaration of decontamination
  - Reprocessing data
- The supplier must keep a dossier of every loan instrument tray
  - Where and when the tray was used
  - All declarations of decontamination
  - Maintenance file



# Implementation of the standard within the hospital

- All parties involved must be informed
  - Operating theatre
    - Must inform CSSD about the surgical procedure
    - All trays to CSSD
  - Purchase department
    - While ordering out they must also ask for the reprocessing information
  - Suppliers
    - Must comply with MDD
  - CSSD
    - Building database and record keeping loan instruments
- General purchase conditions



## Present status of the standard

- Mostly all of the hospitals and suppliers use the standard
- Having the standard makes it easier to discuss the issue of loan instruments



## All problems solved?

- Still having problems with:
  - exotic trays
  - the reprocessing time
  - the provided information
- But we must have ongoing communication with all parties involved to make sure everyone understands the difficulties with the reprocessing of loan instruments and dangers for the patient.



## Conclusion

- The national standard has proven to be a useful tool for organising the loan instruments
- All national associations must be involved in the “making off” the standard
- We are now planning an evaluation of this standard
- The declaration of decontamination can also be used for instruments that are out for repair and replaced by an other instrument (e.g. flexible endoscopes)



**To be, or not to be: that is the question**

**To loan, or not to loan:**  
that is the question of knowing the  
limitations and restrictions on  
reprocessing  
and taking responsibility