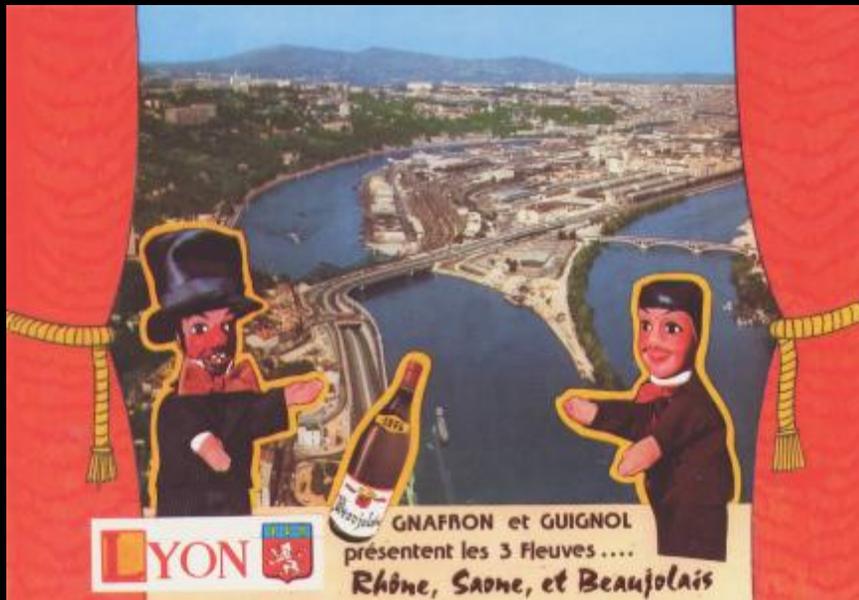


*EFHSS/ SGSV/SSSH
Winterthur, 3-5 July 2003*

How a quality system had to be implemented for the hospital sterilisation, in France ?

Dr Dominique GOULLET
Chairman of AFS
Coordonator of the C.S.
Lyon - France

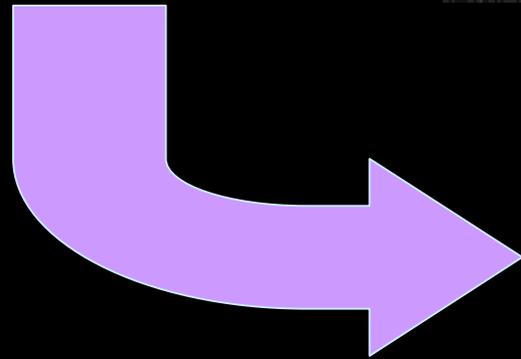




Lyon

LA SAONE, LA COLLINE DE FOURVIERE





1982

Recommandations for
implementation
a CSSD

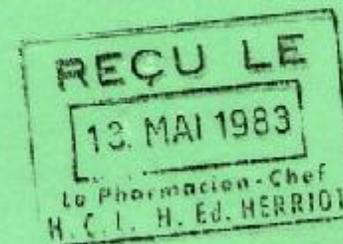
MINISTÈRE DES AFFAIRES SOCIALES
ET DE LA SOLIDARITÉ NATIONALE
MINISTÈRE DE LA SANTÉ

STÉRILISATION

Guide pour l'aménagement, la gestion
et la direction d'une stérilisation
centrale ou d'une centrale d'appro-
visionnement du matériel stérile et
du pansement en milieu hospitalier

FICHE TECHNIQUE D'ORGANISATION HOSPITALIÈRE

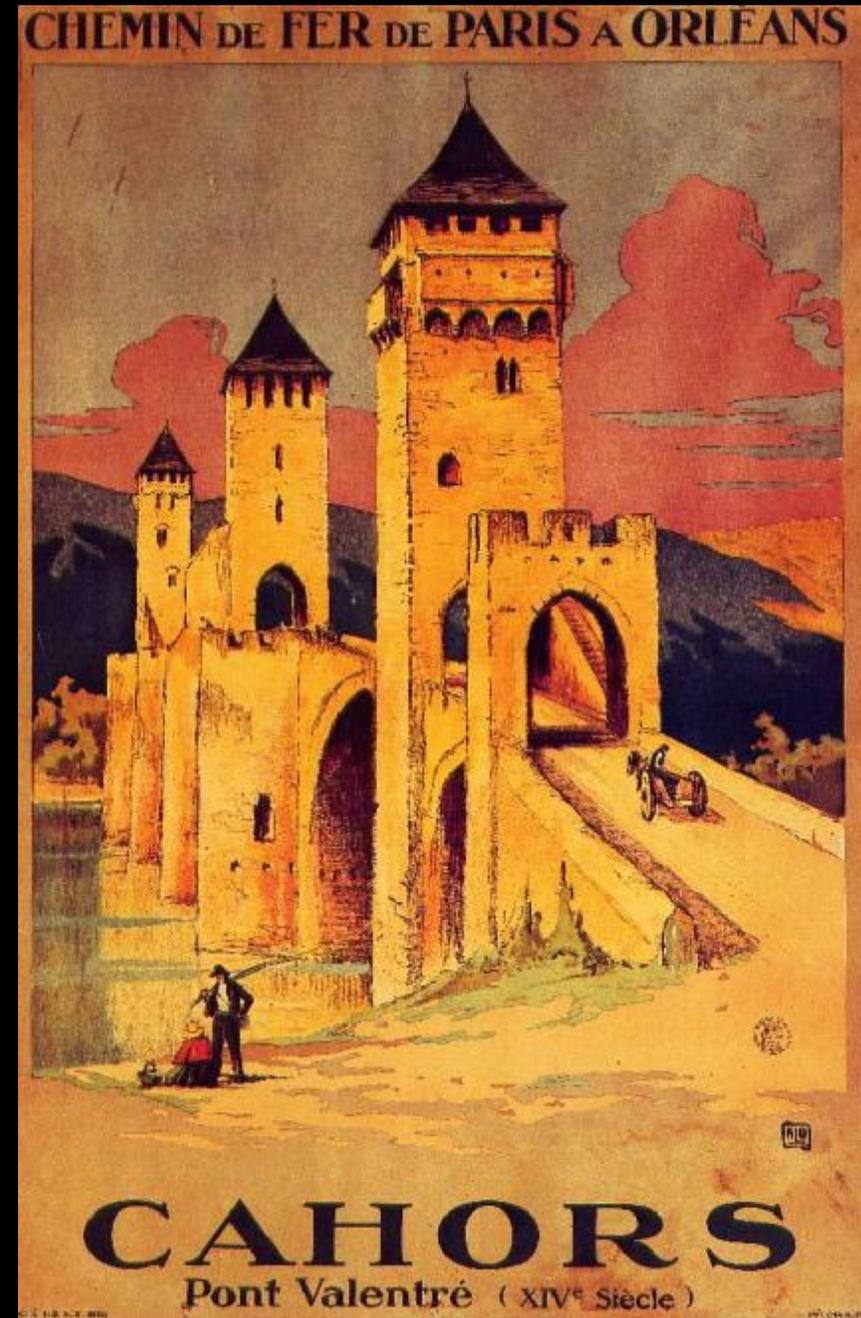
Fiche n° 11



Fascicule spécial n° 82/30 bis

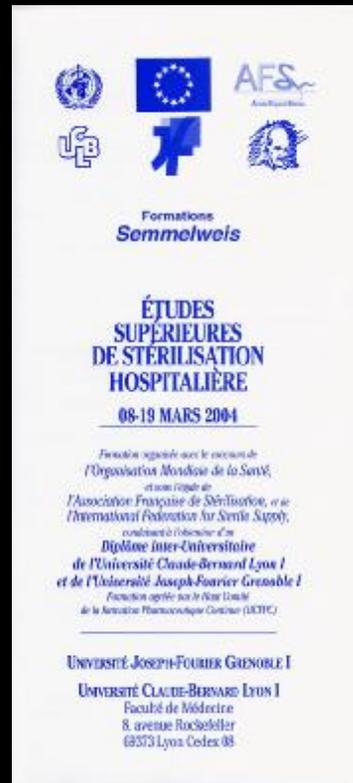
1982

Training on
sterilisation
organized for
hospital staff by
CEPH, recognized
by the Ministry





1993 : premier
Diplôme Inter
Universitaire
organisé par l'
Université de
Lyon/Grenoble
(dans la
Fondation
Mérieux -
Annecy)



The re-use of single use devices is strictly forbidden

- Two circulars (1986, 1994)
 - investigations by authorities
 - sentence of managers, surgeons and pharmacists in some hospitals

1996 : accreditation of the health institutions

- Every health establishment has to be accredited
- Sterilisation is one of the points to be fulfilled

Ordonnance n° 96-346 du 24 avril 1996, portant sur la réforme de l'hospitalisation publique et privée

Three major events

- The **contaminated blood scandal**
- **BSE and CJD** → first circular for the prevention of transmission of NCTA (1994)
- The « **Clinique du Sport scandal** » (Mycobacterium xenopi - 1997)

→ *The health authorities became suddenly aware of the importance of sterilisation !*

1997 : ministry circular for implementing quality in hospital sterilisations

- **The bases are given**
 - quality system to be established
 - validation of the processes to be performed
- **Inspections by health authorities** (Pharmacy inspection) are managed
- → the results are different according to the spots, some are very poor (no central service, dry-heat sterilisation, no validation performed...)
- → some hospitals had to close their Sterilisation Unit

B. KOUCHNER statement, minister of health

« One cannot support the idea that patients may have different qualities of care if the instruments have been processed by industry or by hospital »

1998 : Guide for Good Disinfection Practices

- **critical m.d.**

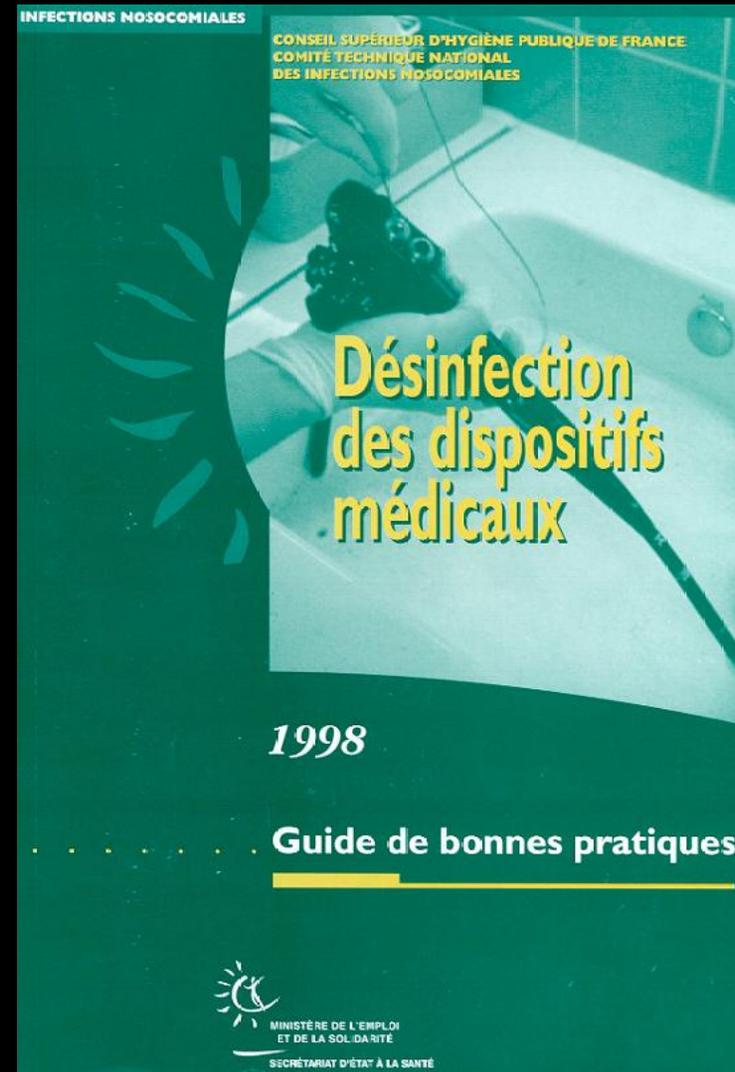
→ **sterilisation
or HL
disinfection**

- **d.m. semi-
critical m.d.**

→ **IN
disinfection or
sterilisation**

- **non critical
m.d.**

→ **LL
disinfection**



Consequences (1)

- In any place where sterilisation is performed, at hospital, the preparation of sterile medical devices is under the responsibility of the hospital Pharmacy

- Sterilisation =

– pre-disinfection	on the spot
+	
– cleaning, checking, packing,	Under the
– sterilisation, monitoring,	responsibility
– distribution and storage	of the
	Pharmacy

Article L 5126-5 CSP modifié par la loi N° 2002-73 du 17/01/02 de modernisation sociale

Consequences (2)

- The management of sterile medical devices at hospital is under the responsibility of the hospital Pharmacy

- purchase
- distribution
- storage
- information

Under the
responsability
of the
Pharmacy

Article L 5126-5 CSP modifié par la loi N° 2002-73 du 17/01/02 de modernisation sociale.

The strength of such a system is that the head of sterilisation has the same power as the surgeon, since both of them are hospital practitioners

Here we are, Pharmacists, coming to you,
in the depths of Faculties, to administer
some....



Who is authorized to work in a CSSD ?

- Pharmacist
- Help-pharmacists (« préparateurs »)
- Nurses
- Help-nurses (« aide-soignants »)
- Technicians : computer, servicing
- Eventually an expert in quality

Trained to sterilisation practices

Consequences (3)

- **The sterilisation of medical devices must be performed in a quality system, defined by the Good Sterilisation Practices**
 - organization
 - premises (surfaces, airborne contaminations...)
 - personnel
 - techniques

Arrêté du 22 juin 2001 relatif aux Bonnes Pratiques de Pharmacie Hospitalière – Ligne directrice N° 1 : Bonnes pratiques de stérilisation

Consequences (4)

- The validation of every processes has to be performed according to
 - NF EN 554
 - NF EN 550
 - NF EN ISO 14 937

➔ *Big market !*

Consequences (5)

- The activity « sterilisation » is subjugated to authorization, after application and inspection of the premises and organization by health authorities (Pharmacy and Conseil de l'Ordre des Pharmaciens inspection)

Décret n° 2000-1316 du 26 Décembre 2000 relatif aux pharmacies à usage intérieur et modifiant le Code de la Santé Publique

Consequences (6)

- **A responsible for quality assurance in sterilisation must be appointed in every institution**
- **A documentary evidence of the implemented quality assurance must be submitted to authorities**

Décret N° 2002-587 du 23 avril 2002 relatif au système permettant d'assurer la qualité de la stérilisation des dispositifs médicaux dans les établissements de santé et les syndicats inter-hospitaliers

Consequences (7)

- All these measures are mandatory
- The hospital managers had to consider them
 - organization in CSSD
 - implementing a quality system
- → plants to be closed
- → groupings
- → sub-contracting with private companies

Authorizations for sterilisation : the results in 2003

- 2908 establishments have a pharmacy
- 1384 have subjugated the authorization for sterilization
- 145 are not authorized (10,5 %)

*mainly for reason of their premises
(quality of air)*

Conclusion

- Some major events have been necessary for the evolution of sterilisation in hospitals
- The rules are very stringent
- Now, sterilisation is performed in a Quality System everywhere

French are amazing : we are fond of liberty, individualism, but we stress on regulations...

-
- We wish other countries such stringent rules so that

sterilisation is recognized
quality = reliability

« The sterility of a product is not negotiable, because the security of the patient is not negotiable »



THE END