



**Berlin, 26 June 2015**

## **Air supply in operating theatres – the French view**

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# Conflict of interest





Phototypie Marcel Delboy, Bordeaux

BORDEAUX - Hôpital Saint-André  
Salle des Opérations M. D.



*BORDEAUX — Hospice et Hôpitaux Pellegrin  
Pavillon Tastet-Girard. Salle d'Opérations*





# French new guidelines – June 2015

2015 - Volanso, C. B. - n° 5 - SF2H - 1 2015-0015 - 304



RECOMMANDATIONS

Qualité de l'air  
au bloc opératoire  
et autres secteurs  
interventionnels

Mal 2015



# French new guidelines – June 2015



## Recommendation 0 (no rating)

**It is highly recommended to analyze a priori risk for the development of an air treatment.**


## Recommendation 15

**It is recommended to analyze a priori risk (eg using a AMDEC or 5M type of method) to identify possible underlying causes of non-conformities of environmental controls performed and the possible corrective measures.**

**Grade B3. Total agreement (p25:9; p50:9)**



# A very light regulation

-  **No specific air treatment mandatory required:**
  - **Old regulation about building designed to received visitors,**
  - **Out of date regulation about volatile anaesthetic gas,**
  - **Decree of 7 January 1993 about outpatient surgery:**

## A very light regulation

### **Decree of 7 January 1993 about outpatient surgery**

- The operating area includes a protected operating area. This area warrants through technical devices, work organization and a specific and adapted hygiene, minimizing the risks to the patient, the surgical team, third parties and the environment, and has the appropriate means to face their consequences. These risks include anesthetic and infectious ones or those related to physical agents used.**
- All operative sector and any protected operating area must be physically demarcated and indicated.**

Hospitals

**Customs 1**

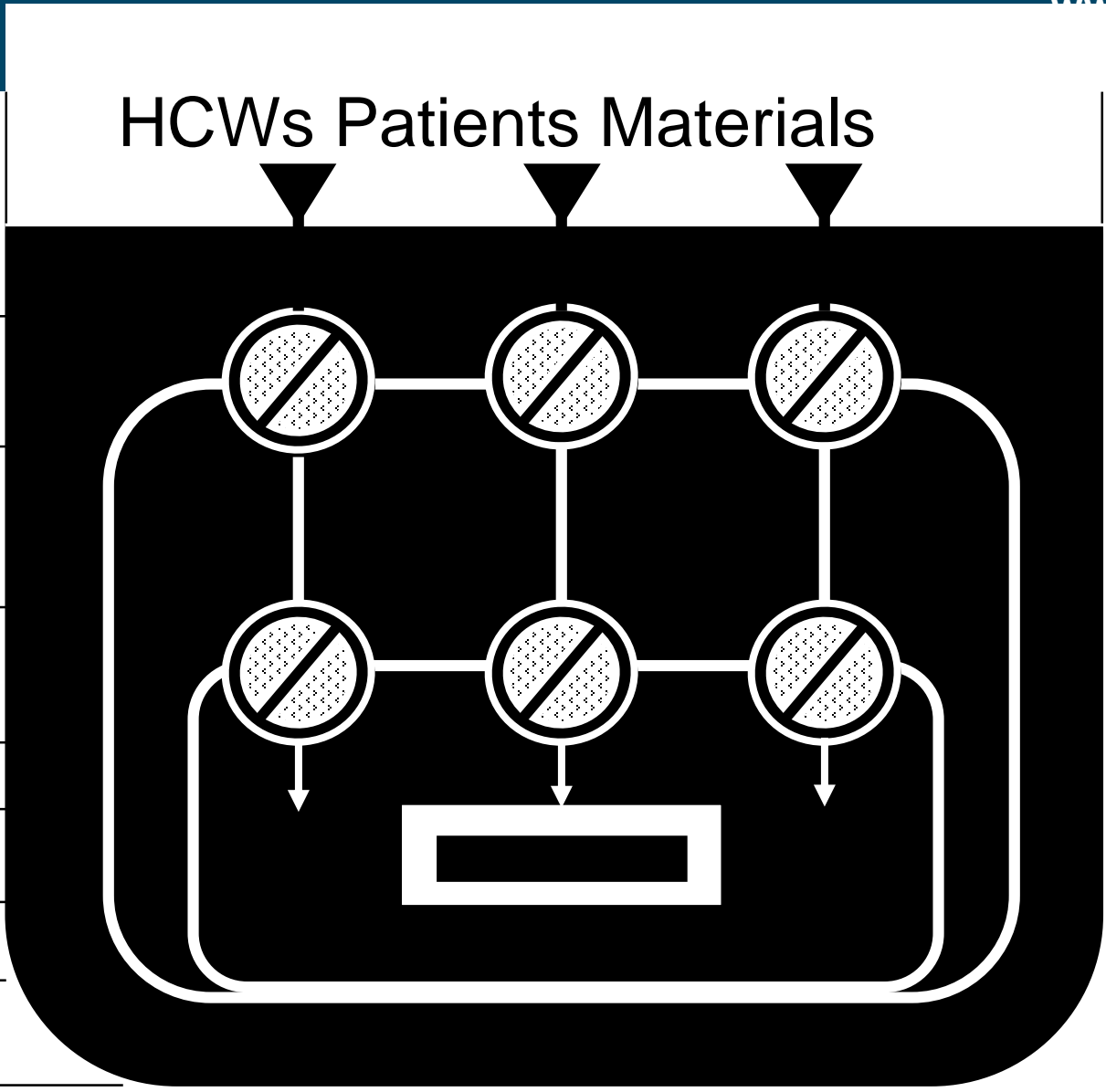
Commun sector

**Customs 2**

Operating room

Drapes

Couloir



Soiled

Clean protection area

Clean

Sterile protection area

Protected

# A strong French standard – April 2013

ISSN 0335-3931

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norme française

**NF S 90-351**

6 Avril 2013

Indice de classement : S 90-351

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ICS : 11.080.01

**Établissements de santé —  
Zones à environnement maîtrisé —  
Exigences relatives à la maîtrise  
de la contamination aéroportée**

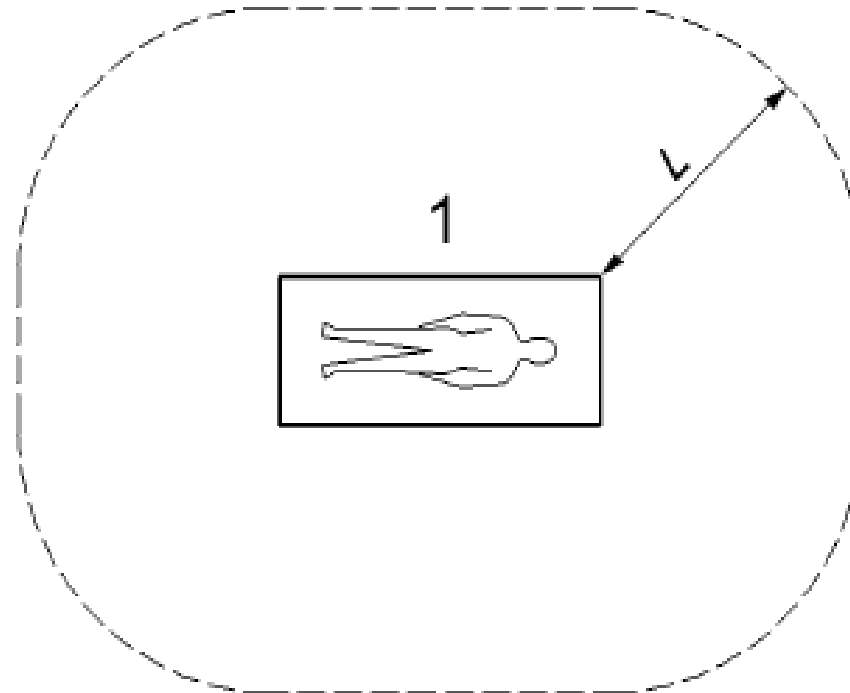
E : Health care institutions — Controlled environment areas —  
Requirements for airborne contamination control

D : Einrichtungen des Gesundheitswesens — Zonen aus kontrolliertem Bereich —  
Anforderungen an die Lenkung von luftgetragener Kontamination

# French standard – April 2013

M	ABDELAZIZ	IHF — INGENIEURS HOSPITALIERS DE France – CHU de Toulouse
DR	ADJIDÉ	SF2H — SOC FSE D HYGIENE HOSPITALIERE
DR	AHO	SF2H — SOC FSE D HYGIENE HOSPITALIERE
MME	ALLOUL-MARMOR	ASPEC
M	BARTOLUCCI	CHU DE ROUEN
M	BIDAR	MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE – DGOS — DG DE L'OFFRE DE SOINS
M	BRUNO	AIR SUR
DR	CAUSSE	CTRE HOSPITALIER INTERCOMMUNAL CRETEIL
M	COLOMBIE	ARCHITECTES INGENIEURS ASSOCIES
DR	FRANCO	AH-HP — HOPITAL ANTOINE BECLERE

# French standard – April 2013



**Protected patient environment – L : 0.5 to 2.5 meters**

# French standard – April 2013

ISO	0,1 $\mu\text{m}$	0,2 $\mu\text{m}$	0,3 $\mu\text{m}$	0,5 $\mu\text{m}$	1 $\mu\text{m}$	5 $\mu\text{m}$
Classe ISO 5	100 000	23 700	10 200	3 520	832	29
Classe ISO 6	1 000 000	237 000	102 000	35 200	8 320	293
Classe ISO 7				352 000	83 200	2 930
Classe ISO 8				3 520 000	832 000	29 300

# French standard – April 2013

<b>Risk class</b>	<b>Particulate Cleanliness class</b>	<b>Particulate Removal kinetics</b>	<b>Microbiological cleanliness class</b>
<b>4</b> Prosthetic ortopedia and burns surgery	<b>ISO 5</b>	<b>CP 5</b>	<b>M1</b>
<b>3</b> Other surgery	<b>ISO 7</b>	<b>CP 10</b>	<b>M10</b>
<b>2</b> OR corridor	<b>ISO 8</b>	<b>CP 20</b>	<b>M100</b>



# French new guidelines – June 2015



## Recommendation 1

**It is recommended to establish an air treatment with unidirectional flow for prosthetic orthopedic surgery to reduce aerobiocontamination. This is in addition to antibiotic prophylaxis which plays an essential role in the prevention of infection for this type of surgery.**

**Grade B1. Strong agreement (p25:7; p50:9)**

## Recommendation 2

**It is highly recommended to set up an air treatment in a versatile operating room. According to the standard NF 90-351 in force, air treatment achieves particulate contamination class at least equivalent to ISO 7**

**Grade A3. Full agreement (p25: 9; p50: 9)**

# French new guidelines – June 2015



## Recommendation 11

**It is strongly recommended to establish a particulate ambient air control (immediate results, standardized method, better reproducibility) whenever an air control system aims to obtain a controlled environment in the operating room and interventional sector.**

**Grade A2. Total agreement (p25:9; p50:9)**

## Recommendation 12

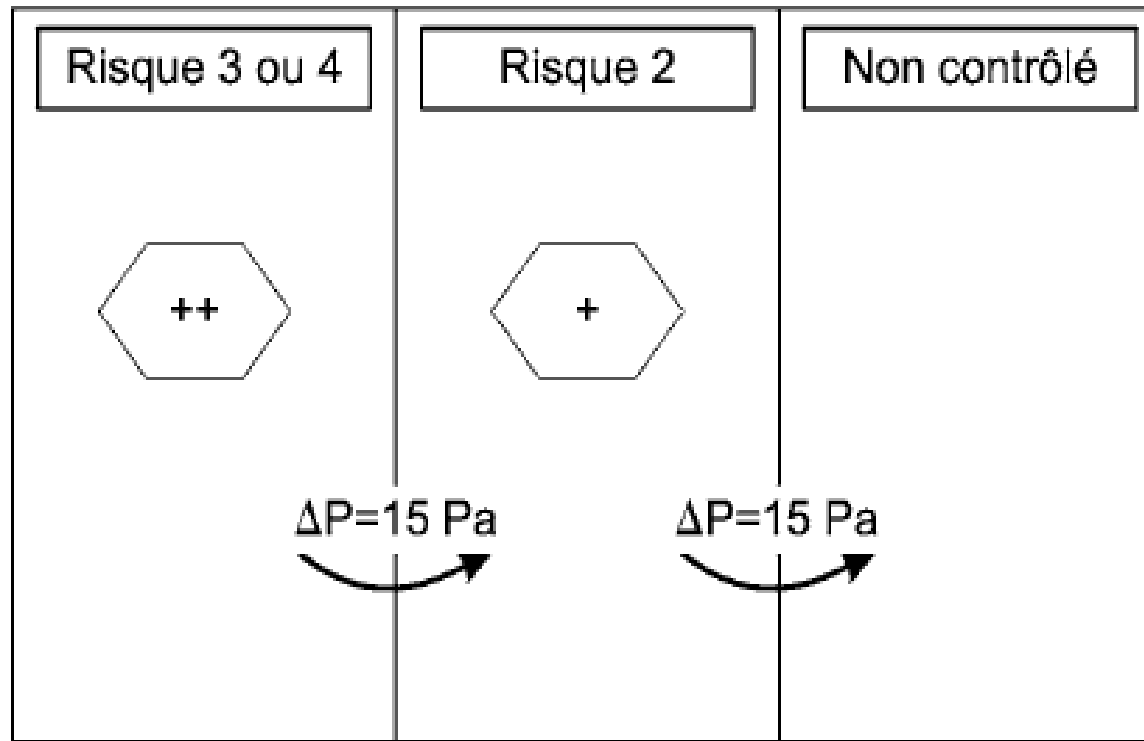
**It is recommended not to do routine microbiological controls air whatever delivery method (unidirectional flow or not unidirectional flow) of air control system.**

**Grade D3. Strong agreement (p25: 7; p50: 9)**

# French standard – April 2013

Risk class	Particulate cleanliness class	Differential pressure (positive or negative)	Temperature Range	Air flow regime of the protected area	Other specifications, minimum value
4	ISO 5	15 Pa $\pm$ 5 Pa	19 ° C to 26 ° C	Unidirectional flow	Area under the flux Air velocity of 0.25 m/s to 0.35 m/s Fresh air rate of the room, not less than 6 volumes / hour
3	ISO 7	15 Pa $\pm$ 5 Pa	19 ° C to 26 ° C	Unidirectional or non-unidirectional flow	Air mixing rate greater than or equal to 15 volumes / hour
2	ISO 8	15 Pa $\pm$ 5 Pa	19 ° C to 26 ° C	Non-unidirectional flow	Air mixing rate greater than or equal to 10 volumes / hour

# French standard – April 2013



Pressure waterfall

# French new guidelines – June 2015



## Recommendation 8

It is recommended that the pressure cascade provides a gradient of  $15 \pm 5$  Pa.  
**Grade B 3. Total Agreement (p25: 9; p50: 9)**

## Recommendation 17

It is recommended for each room boasting an air quality control system, to provide users at least the following witnesses of good works:  
pressure and temperature.  
**Grade B 3. Total Agreement (p25: 9; p50: 9)**

# French new guidelines – June 2015



## Recommendation 21

**It is recommended to monitor and trace the opening day of the room, the displayed parameters such as pressure and temperature. It is recommended to have a written procedure on the measures to be implemented in case of non-conformities.**

**Grade B3. Total agreement (p25:9; p50:9)**

## Centre hospitalier intercommunal de Cornouaille

Bloc médico-chirurgical 541 lits

Quimper (29)

- Hébergement
- Logistique
- Plateau technique
- Urgences SAMU

Restructuration-extension hôpital type Fontenoy

### Hébergement

- 251 lits médecine / chirurgie
- 18 lits néonatalogie
- 12 lits néphrologie
- 15 lits dialyse
- 20 lits chirurgie ambulatoire

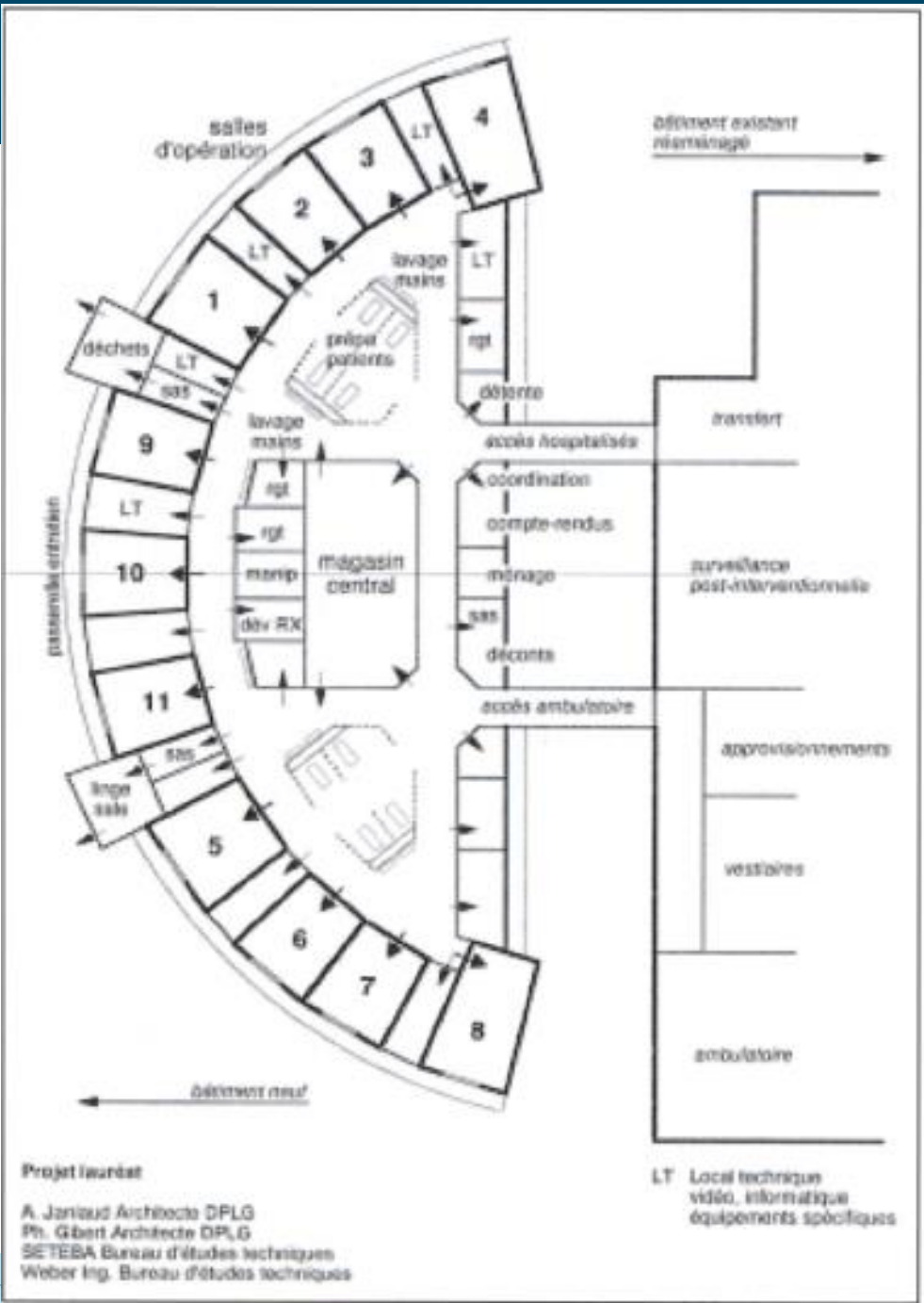
### Plateau technique

- Bloc opératoire 12 salles
- bloc obstétrical
- Stérilisation centrale
- Cardiologie
- Urgences pédiatriques
- Consultations
- Pharmacie
- Explorations fonctionnelles

### Logistique

- Cuisine centrale
- restaurant du personnel
- Magasin





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-









## 2 le plafond ventilo-diffusant CamHosp-R



© Camille Farr



## A Flux d'air traité

Valeurs typiques	0,25 m/s	0,32 m/s
Air neuf traité	2 000 - 2 400 m <sup>3</sup> /h	2 000-2 400 m <sup>3</sup> /h
Air recyclé	6 100 - 5 700 m <sup>3</sup> /h	8 400 - 8 000 m <sup>3</sup> /h
Total sous flux	8 100 m <sup>3</sup> /h	10 400 m <sup>3</sup> /h



## The new madness: The hybrid room

# Conclusion

-  **Air control in operating theatres in France:**
  - **No real change in scientific evidences,**
  - **No data to modify strategy for minimally invasive surgery,**
  - **Low regulation, strong standard,**
  - **Wide professional consensus,**
  - **Improved design and conception quality!**
-  **Some remaining questions:**
  - **How many rooms to equip with ISO 5 level?**
  - **What is the room left for non-unidirectional flow?**

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## NA 041-02-53 AA

### Function rooms (Mirror committee CEN/TC 156/WG 18)

The Working Committee NA 041-02-53 AA "Function rooms (Mirror committee CEN/TC 156/WG 18)" of Heating and Ventilation Technology Standards Committee (NHRS) in DIN deals with standards and standardization projects related to design, construction, acceptance and periodic inspection of ventilation systems in function rooms. These include among others all health service buildings and rooms, which must be supplied with ventilation and air conditioning due to infection hygiene or occupational health, as well as to rooms directly connected to those rooms by doors, corridors/hallways, etc. such as in: - Hospitals; - Clinics; - Nursing homes, - Engaging rooms in doctors' surgeries; - Ambulant surgery centers / facilities; - Dialysis centers; - Facilities for internal and external (service) units for the reprocessing of medical devices (formerly central sterilization "). In the European standardization NA 041-02-53 AA acts as mirror committee to CEN/TC 156/WG 18 "Ventilation in hospitals".


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### Mirrored Committees of NA 041-02-53 AA

Committee ID	Name
CEN/TC 156/WG 18 Secretariat : NEN	Ventilation in hospitals