

Table of technical performance to be achieved in health care institutions (NF S 90-351, Extract from the AFNOR Table B-4-Appendix B):

Area Level	Specific Class of the Area to be protected	Flow Regime	Rate of Air Renewal
4	ISO 5	Unidirectional flow	Greater than 50 vol/h
3	ISO 7	Unidirectional or non-unidirectional flow	25 to 30 vol/h
2	ISO 8	Non uni-directional flow	15 to 20 vol/h
1	<i>(non specific areas)</i>		

(N.B. Excluding the presence of any human element and in the presence of equipment)

Three main area types may be identified: Areas with increased hygiene standards (central sterilisation or pharmacy units), controlled atmospheres (analysis laboratories, aseptic areas, etc.) and risk areas (operating suites, etc.).

Materials that make up the shell of a cleanroom must primarily comply with requirements for airtightness, shock resistance, cleaning, resistance to disinfecting agents, non-retention of particles and non-proliferation of contaminating agents.

For all cleanroom and associated controlled environment activities the international benchmark standard is NF EN ISO 14644. This is supplemented by the standard NF EN ISO 14698 which deals with biocontamination control.

The standard NF EN ISO 14644 defines a cleanroom as being a "*room in which the concentration of airborne particles is controlled and which is built and used in such a way as to minimise the introduction, production and retention of particles inside the room and in which other pertinent parameters such as temperature, humidity and pressure are controlled as necessary.*"

Comparative table of health care activities, the standard NF EN ISO 14644-1, Federal Standard 209 and Good Manufacturing Practices:

NF EN ISO 14644-1	FS 209 E	GMP	Diffusion	Activities
ISO 1	-	-		
ISO 2	-			
ISO 3	Class 1			
ISO 4	Class 10			Operating suite
ISO 5	Class 100	A-B	Laminar Flow (A) Turbulent Flow (B)	Operating suite and central sterilisation area
ISO 6	Class 1,000			Resuscitation, analysis, aseptic areas, patient's rooms and treatment rooms
ISO 7	Class 10,000	C	Turbulent Flow	Resuscitation, resuscitation rooms, sterile rooms, patient's rooms, analysis laboratories, treatment rooms and aseptic areas
ISO 8	Class 100,000	D	Turbulent Flow	Resuscitation rooms, sterile rooms, patient's rooms, analysis laboratories, treatment rooms, aseptic areas, etc.
ISO 9	Class 1,000,000	-		Resuscitation rooms, sterile rooms, patient's rooms, analysis laboratories, treatment room and aseptic areas.

Summary table of the main standards and recommendations followed by the health care sector.

Standards	Section	Description	Date
NF S 90-351		Appendix D	June 2003
NF EN ISO 14644		Cleanrooms and associated controlled environments	
	-1	Classification of air cleanliness	July 1999
	-2	Specifications for testing and monitoring with a view to demonstrating continued compliance with ISO 14644-1	November 2000
	-3	Test methods	February 2004
	-4	Design, construction and start-up	July 2001
	-5	Operations	December 2004
	-6	Terms and definitions	November 2003
	-7	Separative enclosures (<i>clean air hoods, glove boxes, isolators and mini-environments</i>)	December 2004
	-8	Classification of airborne molecular contamination	November 2006