

APPLICATION NOTE

Cleanroom Standards and Classifications

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Cleanroom technology has developed into a specialist field with its own technical journals, its own conferences and exhibitions, and its own language of technical terms and classifications. This application note covers relevant standards and attempts to clarify the myriad classification systems.

Cleanroom Standards

The main cleanroom standards of interest in New Zealand are as follows:

AS 1386:1989

This standard in seven parts has been widely used in New Zealand as a reference for design, operation and validation of cleanrooms.

FED-STD-209E:1992

Until recently, this standard was used throughout the US and by auditors from the US. It was cancelled in November 2001 in favour of ISO 14644, but its classification system will undoubtedly be used for years to come.

ISO 14644 Cleanrooms and associated controlled environments (8 parts)

ISO 14698 Biocontamination control (3 parts)

These 11 documents will make up a set of global cleanroom standards. They are still being developed, with some already released and most of the others available in draft form.

Ref	Title	Status
ISO 14644-1	Classification of Air Cleanliness	Released May 1999
ISO 14644-2	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	Released Apr 2000
ISO 14644-3	Metrology and test methods	Draft under discussion
ISO 14644-4	Design, construction and start-up	Released Apr 2001
ISO 14644-5	Operations	Draft Available
ISO 14644-6	Vocabulary	
ISO 14644-7	Separative devices (clean air hoods, glove boxes, isolators, mini-environments)	Draft Available
ISO 14644-8	Classification of airborne molecular contamination	
ISO 14698-1	General principles	Draft Available
ISO 14698-2	Evaluation and interpretation of biocontamination data	Draft Available
ISO 14698-3	Measurement of the efficiency of cleaning processes	Draft Available

Cleanroom Classifications

Cleanrooms are classified according to the concentration of airborne particles. The following table shows the ISO 14644-1 classification for the main particle sizes of interest together with comparable AS1386 and FED-STD-209E classifications.

ISO Class	Max concentration (particles/m ³ of air) for particles equal to or greater than size shown				FED-STD-209E Class	AS1386 Class
	0.1µm	0.3µm	0.5µm	5µm		
1	10					
2	100	10	4			
3	1000	102	35		1	0.035
4	10000	1020	352		10	0.35
5	100000	10200	3520	29	100	3.5
6	1000000	102000	35200	293	1000	35
7			352000	2930	10000	350
8			3520000	29300	100000	3500
9			35200000	293000		

ISO classes 1-4 are mainly applicable to the semi-conductor industry and we are not aware of any such cleanrooms in New Zealand. Classes 5, 7 and 8 are most common.

The airborne particle concentration in a cleanroom is highly dependent on the occupancy of the room because occupants are major particle sources. So the classification of the cleanroom must be defined at one or more of the room's occupancy states, viz. "as-built", "at rest", or "operational". For example, a cleanroom may be class 7 (= class 10000 = class 350) in the "operational" state and class 5 (= class 100 = class 3.5) in the "at rest" state.

Good Manufacturing Practice (GMP)

There are two methods by which cleanrooms and semi-clean rooms have been specified in New Zealand.

For the Food Industry, MAF have traditionally specified the air filters required. For example air filtration of EU5 or better for processing areas is specified in the Meat Industry Agreed Standard 2 – Design and Construction ⁽¹⁾. This may be appropriate for low-level clean spaces, but is not ideal. The filtration efficiency is only one factor determining the cleanliness of the space – the airflow, the room construction, the room pressurisation and the operations in the room are also important factors. Furthermore, unless the air filters are well manufactured and properly installed, a significant proportion of air can bypass the installed filters.

The other method is to specify the air quality using a cleanroom classification system as described above. The Australian Therapeutic Goods Association use the AS1386 classification. For example, in the code of GMP for medicinal products ⁽²⁾, the general requirement is "Class 7000" which is extrapolated from AS1386. This requirement is commonly used in New Zealand for food processing areas. Also commonly used in New Zealand is the UK (European) "Orange Guide" ⁽³⁾ which defines 4 grades of cleanrooms for manufacture of sterile medicinal products according to air quality in both the "at rest" and "in operation" states.

Orange Guide Grade	At rest		In operation		Max permitted viable micro-organisms /m ³
	Max permitted particles /m ³ equal to or larger than				
	0.5µm	5µm	0.5µm	5µm	
A	3 500	0	3 500	0	<1
B	3 500	0	350 000	2 000	10
C	350 000	2 000	3 500 000	20 000	100
D	3 500 000	20 000	Not defined		200

Beware of using grades for cleanrooms! Although the definitions above are commonly used, other codes for GMP such as TGA ⁽⁴⁾ and MAF – ACVM ⁽⁵⁾ define grades A to D slightly differently.

References

- (1) Industry Agreed Standard 2 – Design and Construction, Animal Products Group, New Zealand Food Safety Authority. Section 5.3
(available on-line at <http://www.nzfsa.govt.nz/meatdoc/meatman/manual-2v>)
- (2) Australian Code of Good Manufacturing Practice For Therapeutic Goods – Medicinal Products, Therapeutic Goods Association, 1990. Page 11.
- (3) Rules and Guidance for Pharmaceutical Manufacturers and Distributors, (known as “The Orange Guide”) Medicines Control Agency, The Stationery Office, London, 1997. Annex 1.
- (4) Australian Code of Good Manufacturing Practice For Therapeutic Goods – Medicinal Products, Therapeutic Goods Association, 1990. Page 56.
- (5) ACVM (Agricultural Compounds & Veterinary Medicines) – Guideline for Good Manufacturing Practice, Ministry of Agriculture and Forestry, Wellington, NZ, 1999, Annex 1.
(available on-line at <http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines>)