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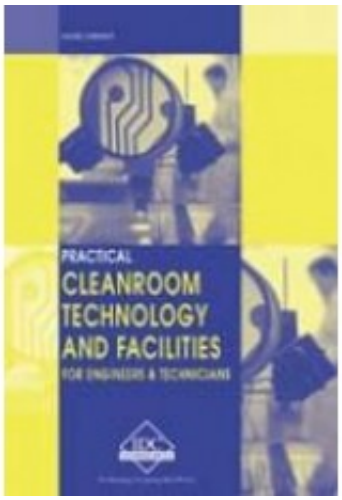
CR-E - Practical Cleanroom Technology and Facilities for Engineers and Technicians



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Short Description

This manual covers working in a controlled environment; handling, storing and using hazardous materials, wet chemicals and gases; increasing your product yield; understanding different cleanroom concepts; controlling contamination from interfering with the production of your product and its end-use performance; codes and legislation governing the design and operation of cleanrooms; hi-purity water; its uses, generation and distribution waste water treatment and personnel safety practices in the cleanroom environment.

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An Overview - Practical Cleanroom Technology and Facilities for Engineers and Technicians

1 Overview of Cleanroom Technology

Overview

Cleanrooms are rapidly becoming a regular feature of the modern industrial landscape. From medicine to semi-conductors, their use is proliferating. Modern processes demand higher and higher yields, in manufacturing, reliability and post manufacturing from their product. In parallel, the drive for miniaturization is making the products more sensitive to contamination. This trend is set to continue. The developing field of ‘nanotechnology’ is likely to even accelerate the demand for cleaner and cleaner cleanrooms. In truth, modern life would be much different without the cleanroom and its products. Supporting the cutting edge cleanrooms is a series of other cleanrooms for the manufacture of cleanroom equipment, materials and consumables.

This book has been developed for students who intend getting involved with cleanrooms. This includes future process engineers, production engineers, research engineers, scientists, project engineers, technicians, operators and maintenance staff.

The subject matter of this course is broad. Complex theory is avoided. Cleanrooms are a combination of series of complex systems. They require of a number of support operations with all their unit operations and sub systems that all have to operate together. A major task in the construction, operation and maintenance of the cleanroom is the interaction of all these supporting operations all the way down to their sub systems.

Achieving today’s standard of cleanliness did not happen overnight. It has been an iterative process driven on by the increased sensitivity of products to contamination.

Understanding Micro-contamination reveals that pure cleanliness is not attainable or even desirable. We can only achieve degrees or classes of cleanliness. Therefore managing Micro-contamination is the name of the game in designing a ‘clean’ manufacturing facility.

The manufacture of ultra pure water is a major process in itself. In a modern facility the production of ultra-pure water and the treatment and disposal of water waste is the greatest investment second to that required for the air handling systems.

The amount of water consumed by today's UPW plants is very high. The lack of water availability is a constraint to the expansion of cleanroom facilities in certain parts of the world.

Finally the cleanroom is required to handle a large variety of hazardous chemicals (gases and wet chemicals) while maintaining the safety of the personnel and the facility. These chemicals often have an extremely high purity standard. This high purity has to be maintained all the way to their point of use.

Despite all the hardware, it is people who make these facilities function. Extensive life safety systems are needed to make it safe for them to work in the facility. Training is vital for the productivity of these people. Personnel are also major source of contamination. Those who work inside a cleanroom need to be fully trained for the task in hand and have a full appreciation of cleanroom technology and facilities. This manual aims to impart this appreciation.

1.1 History of cleanrooms

Contamination control may be traced to the surgical rooms of the early 1900s and the First World War.

The problems were with airborne germs and surface contamination of an infectious nature. New methods of sterilization and decontamination were developed to defeat these microscopic sources of infections. Today operating theatres are considered to be cleanrooms.

The demand for precise navigational devices and missile control systems developed from the 1940s onwards led to the introduction of white rooms. These were the forerunners of today's cleanrooms. This is because efforts were made to control the dust contamination and surface deposits.

During the same period developments were made in high efficiency filters that are vital in the creation and maintenance of today's cleanrooms. NASA was the builders and operators of the world's first cleanrooms.

In the 1990s there were 10,000 cleanrooms in the United States and nearly 30,000 worldwide.

The number of cleanrooms and other controlled environments are growing rapidly due to the continual introduction of contamination sensitive products and processes.

1.2 The need for a cleanroom

Cleanrooms are defined as controlled environments. They and other controlled environments, such as sterile areas, are necessary because of increased product sensitivity to contamination.

Contamination can cause a variety of problems to material, processes and products.

Examples are:

- Surface imperfections such as bumps and dents.
- Mechanical damage such as scratches.
- Optical defects caused by light scattering and blocking.
- Chemical damage or positioning of the material.
- Pathogens, bacteria and other micro-organisms, which lead to infection in food and pharmaceuticals.
- Surface film adhesion or non-adhesion.
- Static electricity destruction by sudden discharges or static electricity.

Reducing contamination will mean an increase in:

Yield: the percentage of devices, which are of an acceptable quality at the end of the manufacturing process.

Reliability: the ability to survive in service.

Integrity: repeatability and accuracy of results in the area of science and research.

The controlled environment is also vital in the field of medicine. When the body’s immune system is compromised by injury or disease, procedure or treatment, a controlled environment must be used to minimize the chances of infection. Hence today’s operating theatres are also controlled environments.

The world without cleanrooms would mean that we could not manufacture, analyze materials or devices or utilize the processes, which are sensitive to the environment.

Quite simply, without cleanrooms the products we take for granted would not exist.

The personal computer would be a pipe dream; medical implants and bacteria free preparations and pharmaceuticals would be prohibitively expensive.

The world we live in is a contaminated place. Contamination in a cleanroom context is defined as:

'Any substance or form of energy that is unwanted and/or produces an adverse effect.'

Put another way:

'Contamination in a cleanroom can also be defined as anything that interferes with the production of the product or its performance.'

A cleanroom is a place where we can control this contamination. A controlled environment is where we can control the temperature, humidity, vibration, static electricity and dust levels.

Our very own little world, like the real world, our cleanroom is highly complex and very dynamic consisting of many interacting parts and systems. All these systems have their own specialization and technologies.

In addition to the physical plant there is the soft side that is vital to the functioning of a cleanroom and that is the human and organization element like safety systems, employee skills and the management of people who work there.

Today's users of cleanrooms include the following industries and services:

- Microelectronics (the control of dust and static).
- Semiconductor (the control of dust temperature, humidity and vibration).
- Data storage (the control of dust).
- Aerospace (the manufacture of aeronautical, electrical and mechanical components).
- Recording studios (the control of noise and vibration).
- Material science (the control of contamination).
- Food processing (the control of contamination and pathogens).
- Research laboratories (the control of cross contamination).
- Precision mechanical & metrology (the control of temperature and humidity).

- Optical, the manufacture of high resolution components (the control of temperature).
- Pharmaceutical (the control of pathogens and cross contamination).
- Biotechnology (the control of cross contamination).
- Medical (the control of infection).
- Hospital operating theatres (the control of infection).
- Nuclear (the control of containment of radioactive escape).
- Automobile components (the control of particle contamination).
- Universities research laboratories (the control of particle contamination).
- Government laboratories (the calibration of equipment for standards).
- Forensic science laboratories (the control of cross contamination).
- The manufacturers of cleanroom material (cleanroom doors, walls, components etc.).
- The manufacturer of cleanroom equipment (HEPA filters pipe material, valves, tools etc.).

The area of interest to each user is placed in the brackets after the description.

1.3 How the cleanroom works?

The cleanroom is a workplace area where the manufacturing process takes place in a controlled environment or medical, pharmaceutical processes take place. Since the outside ambient air contains many forms of contaminations in terms of Particulate contamination or molecular contamination, we must provide a clean working area in which contamination particles or molecules are reduced to a minimum, so that they do not create a disastrous effect on the product or process being carried out.

In a building of manufacture, a separate area is earmarked to have clean environment suitable for the process and sub divided into various bays, chases, equipment and laboratory according to contamination cleanliness class (ISO-14644) and the rooms are pressurized by air flow supplied by the sub systems like HVAC, and assisted systems like Ventilation system chillers, humidifiers, process water systems, make-up and exhaust systems, compressed air systems, electrical systems, safety systems, acid fume exhaust system, etc.

Airflow control changes the room pressurized air as many times as possible, so that the induced, ingressed contamination are carried away from the cleanroom and maintaining proper humidity and temperature. The proper cleanroom procedures adopted right from the design stage to final validation and certification. Since the majority of contaminations are from personnel discipline and movement, certain etiquettes are formulated and adhered to within the

cleanroom environment

1.4 Clean rooms and the semi-conductor industry

The purpose of a cleanroom in semiconductor industry is simple – to protect the process wafers from all forms of contaminations – whether it is an Airborne particulate contamination, or Airborne Molecular contamination or Surface molecular contamination. As the semiconductor features goes down smaller and smaller, there are more stringent contamination controls are adopted and yet not so simple to control. The contributing elements for contaminations, such as human, automated equipments and even process itself bring in lot of chemical contamination in a steady stream; require an absolute control in modern day semiconductor industry.

Microelectronic facilities manufacturing semiconductors have required cleanrooms providing ISO Class 3 and cleaner for wafer fabrication and Class 5 to 8 for auxiliary manufacturing rooms.

Semiconductor cleanrooms today are of two major configurations: clean tunnel or open-bay (ballroom). The clean tunnel is composed of narrow modular cleanrooms that may be completely isolated from each other. Fully HEPA- or ULPA-filtered pressurized plenums, ducted HEPA or ULPA filters, or individual fan modules are used. Production equipment may be located within the tunnel or installed through the wall where a lower cleanliness level (nominally ISO 14644-1 Class 7 or cleaner) service chase is adjacent to the clean tunnel. The service chase is used in conjunction with sidewall return or a raised floor, possibly with a basement return.

The energy consumption in cleanroom in maintaining stringent contamination control is the highest among the other utilities, process machinery.

The cleanroom layout for semiconductor industry needs to be thoroughly analyzed in terms of process flow; airflow pattern, occupancy rate and the contamination control must be brought into even before starting the production. Improving the cycle time and process flexibility must be given enough importance in the layout. Remember an open ballroom type layout may a better option, but the processes demand a Bay & Chase type construction, as well as minienvironments, which may require separate air handling system and other control utilities designed for it. The contamination control must balance the requirements incorporated to achieve a sustainable and quality productions.

Environmental concerns in semiconductor industry

A tremendous amount of raw materials is used in the manufacturing of semiconductors. Many chemicals used in the production process are not expensive but the cost of maintaining these materials in an ultra-clean state can be quite high. This envisages the close monitoring of usage, the minimization of consumption, the contaminations emanating from these chemicals and their control in cleanroom. Incorporating the relevant equipments, machinery for the process of recycling and reprocessing techniques may involve additional expenditure.

The factual information is that a typical semiconductor industry producing six inch (150mm) wafers uses not only 240,000 kilowatt hours of electricity, but also uses 2 million gallons (525,000 litres) of water every day. These figures may shoot up for 8 inches and 12 inches wafers production even more. On average, the manufacturing of just 1/8-inch of a silicon wafer requires about 3,787 gallons (1000 litres) of wastewater, not to mention 27 pounds (12.2 kg) of chemicals and 29 cubic feet (0.8 cu.m) of hazardous gases. The fab facility design must take into account of these facts, which are essential guidelines for cleanroom in semiconductor industry.

We will study more in details in subsequent chapters about cleanroom construction. Just remember that the cleanrooms are not identical in all form of semiconductor products and the design must be varied to suit the different process and products.

1.5 Cleanrooms and the pharmaceutical industry

The cleanroom design in Pharmaceutical industry differs from the cleanroom design in semiconductor industry. The preparation of pharmaceutical, biological and medical products require cleanrooms to control the viable (living) particles that would produce undesirable bacterial growth and other contaminants.

In general, the pharmaceutical cleanrooms must follow the US based GMP (Good Manufacturing Process) and the product must pass the inspection of US based FDA (Food and Drug Administration).

In a Biomanufacturing and pharmaceutical cleanrooms, the aseptic process area is arranged from highest pressurization to other areas arranged with lesser pressurization. The pressure difference can be in the range of 0.05 to 0.06 inches of water between adjacent rooms. The rooms are separated by air classification and air pressure differences via airlocks.

The cleanrooms require lower pressurization than the adjacent area of

containments area with Pathogens and toxic materials and the airlocks are maintained at a slightly higher pressure than the adjacent rooms.

GMP standard suggests a minimum of 20 air changes per hour (ACH) for rooms with an air particulate classification, with exposed sterile product under a unidirectional flow hood or inside an ISO 14644-1 Class 5 barrier enclosure. US GMP standard currently require only two classes: ISO 14644-1 Class 5 for sterile product exposure, and ISO 14644-1 Class 8 for adjoining spaces. However, it is common practice for places with exposed products to have an ISO 14644-1 Class 5 unidirectional flow zone inside an ISO 14644-1 Class 7 room.

The Barrier technology is another cleanroom within a cleanroom, where higher pressure levels are maintained in smaller areas to reduce capital and operating cost. Applications vary widely based on product, process equipment, and throughput volume. Sterile barriers are typically positive-pressure envelopes around the filling equipment with multiple glove ports for operator access, constructed of polished stainless steel with clear rigid view ports.

Other barrier applications offer operator protection from potent compounds while maintaining a sterile internal environment. These tend to be total containment isolators with completely contained product transfer ports. All internal surfaces are sealed from the external environment or operator exposure. Because of potential chamber leaks, its internal pressure may be kept negative compared to the ambient space, via exhaust fans.

Pharmaceutical product manufacturing facilities require careful assessment of many factors, including HVAC, controls, room finishes, process equipment, room operations, and utilities. Flow of equipment, personnel, and product must also be considered.

1.6 Cleanrooms and Medical and life sciences

Medical Device Manufacturing is an organization dedicated to the assembly, packaging and sterilization of medical devices.

Under USP 797 regulation, all compounding pharmacies are required to protect their products by utilizing laminar flow benches within a cleanroom. Cleaner facilities are required for compounded Sterile Preparations.

Cleanroom compliance

The current air cleanliness requirement for a Compounding Cleanroom is an ISO

Class 8. A separate ISO Class 5 Device is required for the compounding of patient preparations. All sterile compounding is to be performed in an ISO Class 5 Device surrounded by an ISO Class 7 or ISO Class 8 Cleanroom Buffer Zone. “Risk Level” determines the required ISO cleanroom air cleanliness classification. In order to set your ISO Cleanroom Classification you must first determine your Risk level.

The Risk level can be classified as:

Low risk level – requiring ISO Class 5 Laminar flow workbenches, which are to be located inside a ISO Class 7 or 8 cleanrooms and the anteroom leading into cleanroom must be an ISO Class 8 cleanroom.

Medium risk level – requiring ISO Class 5 Laminar flow workbenches, which are to be located inside a ISO Class 7 cleanrooms and the anteroom leading into cleanroom must be an ISO Class 7 cleanroom.

High-risk level – requiring ISO Class 5 Laminar flow workbenches, which are to be located inside an ISO Class 5 cleanrooms and the anteroom leading into cleanroom must be an ISO Class 7 cleanroom.

Barrier Isolator Compliance

The ISO Standard for Barrier Isolators is addressed in ISO 14644-7.

A Choice between a Cleanroom and a Barrier Isolator must be determined based upon your process. Cleanrooms can be expensive spaces. A self-contained, controlled, clean environment enclosure, called a Barrier Isolator, around a critical care process area can be an economical alternative to a Cleanroom.

This separative device is a generic term defined as “equipment using constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume.”

Process isolation enclosures called Q/PECS units are designed to control of air cleanliness, airflow speed and direction, temperature, relative humidity, exhaust flow, sterilization and neutralization, and inert atmosphere. Such units have enclosed laboratory experiments; pilot plant processes, and fully integrated manufacturing processes – all without people inside. Operators interact through air curtains, glove ports, transfer devices, half suits, and remote manipulators.

The life sciences industry calls them isolators or barrier technologies. No matter

what they are called or where they are used, these are the common benefits: They protect product from people contamination and people from product contamination; they protect product from product cross-contamination; they assure protection by reducing or eliminating outside influences; and they provide an enclosed process environment for quality-level achievement. End-use applications include compounding IV solutions, sterility testing, preparing live vaccines, high-accuracy powder weighing, plant tissue laboratory research, robotic sampling, cell culture operations, ampoule filling, nuclear medicine compounding, handling of toxic substances, micro mechanical work, and microchip processing.

1.7 The cleanroom as a system and unit operations

To achieve and operate/maintain the cleanroom environment a combination of many different systems must function together. It is a dynamic system but has to operate in a stable manner to be effective. See Figure 1.1 for a system description of a cleanroom.

Figure 1.1

Typical Wafer fab systems and sub-systems.

In all types of cleanrooms, the main parameters to be controlled are:

- Temperature must be controlled at 22.3°C with plus or minus 0.3°C tolerance.
- Relative humidity must be controlled e.g. 40% RH with plus or minus 3% variation.
- Pressure control positive 0.0125 mm water column (WC) relative to entry corridors and subfab.
- Vibration e.g. 2000 micro inches per second.

To achieve the above parameters the following systems are required:

- Air-conditioning system (chillers and boilers)
- Make up air systems (scrubbed exhaust systems)
- Exhaust Systems
- Cooling water and backup cooling water systems
- Sprinklers and Fire Control Systems
- Cooling water

- Condenser water system
- Smoke detection systems
- Electrical system
- Emergency power systems
- UPS (Uninterruptible Power Supply)
- BCDS (Bulk Chemical Delivery Systems)
- Waste collection systems
- Waste treatment plant Acid treatment plant (AWN)
- High Purity Water Treatment
- FMS (Factory Management System) for the control of all the process plant
- LSS (Life safety systems Public address gas detection)
- Fire safety systems (sprinklers/smoke protection systems)
- Environmental protection systems
- Boiler house
- Chiller house
- Ultra pure water (UPW) production facility
- Nitrogen plant or storage facility
- Bulk gas storage facility
- Gas pad
- Waste water treatment facility (AWN)
- HPM rooms. Hazardous production material rooms
- Bulk chemical storage facility
- Warehousing for gases and wet chemicals

Depending on the processes involved in manufacture within a cleanroom environment, some of the above facilities, systems may be added or deleted. A cleanroom designer will specify the requirements once the need is determined.

1.8 Cleanroom Standards – Old and New

USA Semiconductor/microelectronics Company needed a standard set up for their manufacturing activities and products as early as 1960. Subsequently, Federal Standard 209 was formulated in 1963.

This Federal standard is a document which gives mainly information on the airborne particles required to specify the quality of cleanrooms, and also gives the methods used to check what concentrations are present. It does not give any information on how a cleanroom should be operated.

This information had been included in a series of Recommended Practices written by the Institute of Environmental Sciences, the same Institute as has

written the Federal Standard 209.

Table 1.1 shows Federal standard 209 class limits started with 0.5 microns or larger. It gives only inch units for measurement, not in metric measurements.

Table 1.1

Federal Standard 209

Class	**Maximum number of particle /cft**					**Typical uses**
	0.1mm	**0.2mm**	**0.3mm**	**0.5mm**	**5 mm**	
1	35	7.5	3	1		Integrated circuits
10	350	75	30	10	NA	Integrated circuits
100	NA	7502	300	100	NA	Miniature ball bearing, photo labs
1000	NA	NA	NA	1000	NA 7	Medical implants
10000	NA	NA	NA	10000	70	Colot TV tubes, Hospital operating rooms
100000	NA	NA	NA	100000	700	Ball bearings

Federal standard 209 E was revised in 1992, including even lesser particle than 0.5 microns and included a metric measurement too.

Table 1.2 shows the final version of FS 209 E with FS 209 A to D classification included and SI version of classification with letter “M”:

Table 1.2

Federal Standard 209E Class Limits

FS 209E-CLASS LIMITS

Class Name		**>=0.1mm**		**>=0.2mm**		**>=0.3mm**		**>=0.5mm**		**>=5.0**
SI	Eng	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3

M1		350	9.91	75.7	2.14	30.9	0.875	10.0	0.283	---
M1.5	1	1240	35	265	7.50	106	3.00	35.3	1.00	---
M2		3500	99.1	757	21.4	309	8.75	100	2.83	---
M2.5	10	12400	350	26.5	75	1060	30.0	353	10.0	---
M3		35000	991	7570	214	3090	87.5	1000	28.3	---
M3.5	100	---	---	26500	750	10600	300	3530	100	---
M4		---	---	75700	2140	30900	87.5	10000	283	---
M4.5	1000	---	---	---	---	---	---	35300	1000	247
M5		---	---	---	---	---	---	100000	2830	618
M5.5	10000	---	---	---	---	---	---	353000	10000	2470
M6		---	---	---	---	---	---	1000000	28300	6180
M6.5	100000	---	---	---	---	---	---	3350000	100000	24700
M7		---	---	---	---	---	---	1000000	283000	61800

Table 1.3

ISO Standard 14644-1 Class Limits

ISO Classific ation Numberto	**Maximum concentration limits(Particles/m3 of air) for particles equal and larger than the considered sizes shown below**					
	>= 0.1µm	**>= 0.2m**	**>= 0.3µm**	**>= 0.5µm**	**>= 1µm**	**>= 5.0µm**
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000

Though the new standard is being adopted internationally, there are countries where older version of standards are followed and slowly changing over to ISO 14644.

Tables 1.4-1.7 are shown to assist in this conversion.

1.9 Comparison of Cleanroom Standards

Table 1.4

ISO 14644-1

ISO 14644-1

Classification Number	Maximum Concentration of Particles (Particles/m^3)					
	?0.1mm	?0.2mm	?0.3mm	?0.5mm	?1mm	?5mm
ISO Class 1	10	2	---	---	---	---
ISO Class 2	100	24	10	4	---	---
ISO Class 3	1000	237	102	35	8	---
ISO Class 4	10000	2370	1020	352	83	---
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7	---	---	---	352000	83200	2930
ISO Class 8	---	---	---	3520000	832000	29300
ISO Class 9	---	---	---	35200000	8320000	293000

Table 1.5

FS 209E

Federal

Standard		**Maximum Concentration of Particles (Particles/m^3)**					
209E							
SI	**ENG**	ISO	?0.1mm	?0.2mm	?0.3mm	?0.5mm	?5mm
M1			350	75.7	30.9	10	---
M1.5	**1**	Class 3	1240	265	106	35.3	---
M2			3500	757	309	100	---
M2.5	**10**	Class 4	12400	26.5	1060	353	---
M3			35000	7570	3090	1000	---
M3.5	**100**	Class 5	---	26500	10600	3530	---
M4			---	75700	30900	10000	---
M4.5	**1000**	Class 6	---	---	---	35300	247
M5			---	---	---	100000	618
M5.5	**10000**	Class 7	---	---	---	353000	2470
M6			---	---	---	1000000	6180
M6.5	**100000**	Class 8	---	---	---	3350000	24700
M7			---	---	---	1000000	61800

Table 1.6

EU cGMP Grade

EU	**ISO**	**Fed Std**				
CGMP	**14644-1**	**209E**	**Maximum Concentration of Particles (Particles/m^3)**			
Grade			At Rest		In Operation	
			?0.5mm	?5mm	?0.5mm	?5mm
A	**Class 5**	**100(M3.5)**	3500	0	3500	0
	(at Rest)					
B	**Class 5**	**100(M3.5)**	3500	0	350000	2000
	(at Rest)				(Class 7)	
C	**Class 7**	**10000**	350000	2000	3500000	20000
	(at Rest)	**(M5.5)**			(Class 8)	
D	**Class 8**	**100000**	3500000	20000	Not defined	Not defined
	(at Rest)	**(M6.5)**				

Table 1.7

BS 5295

BS 5295 Cleanliness Class	**Maximum permitted number of particles per m^3**					
	ISO 14644-1	0.3 mm	0.5 mm	5 mm	10 mm	25 mm
C	Class 3	100	35	0	NS	NS
D	Class 4	1000	350	0	Ns	NS
E	Class 5	10000	3500	0	NS	NS
F		NS	3500	0	NS	NS
G	Class 6	100000	35000	200	0	NS
H		NS	35000	200	0	Ns
J	Class 7	NS	350000	2000	450	0
K	Class 8	NS	3500000	20000	4500	500
L	Class 9	NS	NS	200000	45000	5000
M		NS	NS	NS	450000	50000