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THE CLEANROOM

MONITOR

The Scottish Society for Contamination Control

February 2007

Issue 57

CHINESE CLEANROOMS

ASPEC GUIDELINE

PD6609:2007

CLEANROOM COURSES

THE INDUSTRY

CHINA

CLEANROOM TECHNOLOGY: HISTORY AND DEVELOPMENT



Drying of Chinese traditional medicine used to treat stomach discomfort

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China is a relative newcomer to cleanroom technology. It has only a history of around 20 years in design and construction of cleanrooms. However, the building of new cleanrooms is increasing rapidly in the fields of microelectronics, pharmaceutical and medical care. In addition, biosafety labs and hospital operating rooms have shown a recent large and growing demand.

Da Qian Wang, Deputy General Secretary of Chinese Contamination Control Society (CCCS) provides an overview with statistical information in *The History and Development of Cleanroom Technology in China* on pages 2 to 5.

The History and Development of Cleanroom Technology in China

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1. Introduction

China is a relative newcomer to cleanroom technology. It has only a history of around 20 years in design and construction of cleanrooms. However, the building of new cleanrooms is increasing rapidly in the fields of microelectronics, pharmaceutical and medical care. In addition, biosafety labs and hospital operating rooms have shown a recent large and growing demand.

2. The History of Cleanroom Technology

The following are a few of the key dates in cleanroom technology development in China:

1. In early 1961, the first HEPA filter was produced in China.
2. In 1970, the first cleanroom reaching cleanliness classification 10,000 according to FED 209A, in the 'at-rest' state, was established by using domestic HEPA filters.
3. In 1984, an important national standard for cleanroom design was written. This was "Cleanroom Design Code" GBJ73-84, which basically reflected the FED 209B standard. Other cleanroom related standards were also written, such as:
 - "Test Method of High Efficiency Filter Media", GB6166-85;
 - "Test Method of Particle Counter Performance", GB6167-85;
 - "Test Standards for Laminar Flow Bench", GB6168-85.

It is probably worth mentioning that the "The Test Method for Air Filter used in General Ventilation", developed in China, was the first one in the world to test the filter efficiency by using outdoor air with desired particle sizes.

4. In 1980s, large-scaled integrated circuit (IC) production started to flourish in China. Since then, more and more IC plants for the microelectronics industry have been established with more sophisticated technology. These have the strictest particle control and are the highest quality of cleanrooms. They will now be discussed in more detail.

3. Cleanroom Related Industries and Their Development

As is known, China is becoming a major manufacturing base in the world. Shown in Table 1 is an illustration of the growth of the microelectronics industry:

Table 1 IC production in China between 2000 to 2005

	2000	2001	2002	2003	2004	2005
IC Made in China (pcs in 100m)	58.8	63.6	96.3	124.1	211.5	265.8
Growth Rate (%)	41.7%	8.2%	51.4%	28.9%	70.4%	25.7%
IC Sales in China (pcs in 100m)	42.2	32.6	88.8	124.0	207.3	265.8
Growth Rate (%)	70.6%	- 22.7%	172.4%	39.6%	67.2%	28.2%

Between 2000 to 2005, the IC turnover in mainland China maintained a fast and sustained development, growing four-fold in five years, with an average annual growth rate of over 30%. In 2005, the turnover in the mainland Chinese market reached 38 billion euros, a 30.8% growth. Its share in the world also increased from 1.2% to 3.7%, and it became one of the highest growth regions in the world. In Table 2, one can see that the technological lag between the world and China is narrowing in IC production.

Table 2 The history of various diametric IC production lines in China

Wafer Diameter	Year in Production	Year of First Manufacture in the World	Difference in Years
2"	1978	1966	12
3"	1980	1972	8
4"	1988	1975	13
5"	1992	1982	10
6"	1995	1986	9
8"	1999	1988	11
12"	2004	1999	5

Also during the last five years, the number of IC production lines have increased rapidly, as shown in Table 3.

Table 3 A comparison of IC production line number

IC Production Lines in China	2000	2005
Wafer Diameter	Number	Number
12"	0	1
8"	1	9
6"	3	8
5"	6	8
4"	15	14
Total	25	40

Up until now, about 33 manufacturers with 6 inch wafer, and larger, IC production lines are under construction in China. Please refer to Table 4 for details. It is predicted that the annual growth rate of the turnover of IC in China will reach 26.4%, in the next five years, i.e. between 2006 to 2009.

Table 4 The number of IC production lines under construction

Wafer Diameter	Number
12"	5
8"	15
6"	13
Total	33

It is estimated that the cleanroom market in the microelectronics industry in the next several years will reach a few hundred million euros each year.

With the fast development of high-tech industries, and fast expansion of manufacturers such as TFT displays, the demand for cleanrooms maintains a continuous increase. In addition, the healthcare-related fields, such as pharmaceutical, medical devices, and operating rooms also shows a very strong growth.

It is predicted that the pharmaceutical industry will maintain a 9% to 10% annual growth rate from now until the year 2010. Within the next 5 years, the number of pharmaceutical plants that have passed GMP certification will shrink from 4500 to 1000. However, the financial investment in pharmaceutical production from both domestic and foreign investors will enjoy substantial growth in the near future. It is estimated that the cleanroom market in pharmaceutical and biosafety labs is around a few hundred million euros each year in the next several years.

With the aging of the population in China, more and more money is being spent in health care. As we know, China has the largest population in the world, but its share of money spent in medical care is very small in comparison with its population. So, the potential in this field is very large. There are over 10,000 medical device manufacturers in China. In the year 2005, the total product value reached 2.4 billion euros, and the total turnover reached over 8 billion euros. The average annual growth rate is 15%. In the field of medical devices, the global players are promoting their advanced technology and new materials in China. Since the outbreak of SARS, and more recently bird flu, China has put a big emphasis on disease control and prevention. Over 100 new biosafety level 3 labs are being planned across China, for research into ways to control various infectious diseases. There are around 15,500 hospitals across China. Two thirds of them either need improvement of the existing operating rooms into clean ones, or the building of new ones. This is a market of several billion euros in the next 5 years.

China is now at a stage of enjoying the sustained development that has occurred over the last 20 years. China is now the 4th largest economic entity in the world, and the second largest foreign investment destination. However, as we see it, this trend is expected to continue due to the fact that the economy is still rather low if calculated as income per head, or compared with the population. By our estimation, the cleanroom market is worth over one billion euros each year for the next five years.

Some world-famous filter manufacturers also see the trend. They have established their production plants in China for products sales in China and the world market. These filter manufacturers include: Camfil Farr Filtration from Sweden; Cambridge Filter and Nippon Muki from Japan; AAF, Fedders and Filtrair Air Filter from USA; ITC and CTK from Korea; AFPRO from the Netherlands, and Freudenberg from Germany.

4. The Chinese Contamination Control Society and its Activities

The Chinese Contamination Control Society (CCCS) was created in 1982 by China Electronics Engineering Design Institute (CEEDI) due to the fact that the microelectronics industry was enjoying fast growth and needed more and more cleanrooms. CEEDI was one of the leading designers of microelectronic cleanrooms at that time. Also, as is the usual practice, the President of CEEDI, after stepping down from his position, would become the chairman of CCCS. Since CEEDI was under the Ministry of Electronics, now part of the Ministry of Information Industry, so CCCS is a branch of Chinese Institute of Electronics, whose chairman, as normal, is the retired minister of the Ministry of Information Industry. You can therefore see why there is a strong government background of CIE, as well as CCCS. In 1989, CCCS was approved by the government body, and became a member of the International Confederation of Contamination Control Societies (ICCCS).

There are two journals produced by CCCS: Contamination Control and Air-Conditioning Technology, and Cleanroom World. The first one emphasizes technical papers, while the second one emphasizes information and activities. There are four websites under the control of CCCS. They are: www.cccs.org.cn, the website for CCCS; www.cleanroomshow.com for information about cleanroom exhibitions; www.jjsxxx.com for demand and supply information related with cleanroom facilities; www.craa-ctc.org.cn, the website for the Cleanroom Technology Committee of China Refrigeration and Air-Conditioning Association.

CCCS is also responsible for the Cleanroom Technology Committee under the China Refrigeration and Air-Conditioning Industry Association (CRAA). This committee is active in the establishment of industrial standards, such as filter standard. Under CRAA, industrial standards are published, such as CRAA standards for the devices and facilities used in the cleanrooms.

CCCS is mainly active in education, symposium and exhibition, and cleanroom standard establishment. These are now discussed.

4.1 Educational Program Under CCCS

To promote cleanroom knowledge and technology, CCCS has been teaching a basic cleanroom educational course since 2003. An advanced course has been developed and started in 2004. Both courses have a very wide range of information taught. This includes: design, construction, operation and testing of cleanrooms; testing instruments and sampling methods for both particle and microorganisms; biosafety cleanroom and labs; pricing of cleanroom projects etc. The courses cover all kinds of requirements for different applications, such as the cleanrooms for pharmaceutical industry, microelectronics industry, various labs, and operating rooms for hospitals. The basic course takes over 36 hours in class, taking around three to four days,

including the last half day for exam. The advanced course takes over 40 hours in class, taking around five or more days, including the last half day for an exam.

The cleanroom technology engineer certification programs implemented by CCCS are under the authorization of the Chinese Association of Science and Technology for the specialized training of personnel working in the field of cleanroom technology, which is not available from other organizations or bodies. Most of the students are the technicians and engineers from cleanroom contractors, and some of them are maintenance engineers that work with cleanroom users. Up till now, about 800 students have participated in the basic course, and 500 in the advanced course. Among the latter, 350 students received their certificates as cleanroom engineers. Students passing the advanced course are keen to obtain a certificate giving them the title 'Cleanroom Engineer', as this gives them a strong advantage when they are looking for a job in the cleanroom field.

4.2 Cleanroom Standards

Under a strong push from CCCS, a new committee called Cleanroom Technology Committee has just been formed under the Standardization Administration of China (SAC), the only organization representing China as the member in ISO. The cleanroom-related standards in existence need improvement. Nowadays in China, there are various standards relating to cleanrooms, such as Cleanroom Design Code, Cleanroom Construction Acceptance Standards, Hospital Design Standards, Hospital Clean Operating Room Construction Standards, GMP, Animal Lab Facility Standard, GMP for Healthy Food, and GMP for Veterinary Production. However, these standards have certain disadvantages as we see them today. First, most of them still use the old FED209E system instead of the new ISO 14644 series system. Secondly, the standards are too strict and too detailed in general. These bind the hand of the user, which is not considered good for technology development. Therefore, the purpose of this committee is to introduce the international standards for cleanroom e.g. ISO 14644 and 14698 series, into China. The expert team for the Cleanroom Technology Committee is from CCCS. We plan to adopt these international standards fully as national standards, but first as the standards of the Chinese Association of Standardization. To do this will help remove the technical barrier between China and the rest of the world, as more and more foreign investment in cleanroom construction in China is expected. The establishment of the Cleanroom Technology Committee under the SAC would be one solid step to serve this purpose.

4.3 Exhibitions

Sponsored by CCCS, a cleanroom exhibition is held twice a year in China. Usually one is in Shanghai, or a place close to Shanghai, or Beijing, and another one is in Guangzhou. Suzhou is a city very close to Shanghai, which is the origin of traditional the Chinese garden and what is called water villages, i.e. houses along the sides of rivers. Due to its favourable weather and easy access to land and sea transportation, this region is famous as a manufacturing base of foreign companies and/or joint ventures. Our cleanroom show is held once a year in Suzhou Expo, a modern international exhibition centre.

4.4 International Interchange

CCCS would like to facilitate the business of foreign companies in China. Foreign companies are welcome to show their products and services in our exhibitions. The promotion of foreign companies can also be done through our journals. A special issue in our journal for UK companies and products can be published.

Through the introduction of CCCS, a joint venture between a famous filter manufacturer AFPRO and one of CCCS members, Yatai Group, was just established. This joint venture will result in the manufacture of up to three hundred thousand fine filters each year, which are to be sold mainly in Europe. By means of production in China, their production costs will be reduced as much as 30%, mostly due to the low labour costs in China. The Yatai Group manufactures air-conditioning systems and devices used in cleanrooms, such as clean benches and air showers. In addition, they have huge new workshops ready for various processes. The above-mentioned joint venture will rent some of their existing workshops in addition to equal cash investment by both sides. The Yatai Group has a school which enrolls nearly 10,000 students, with courses in mechanics, electronics, car maintenance etc., so, any production or assembly line in their place would not lack technical workers. Yatai is just one of CCCS members. CCCS has nearly 300 members across China. CCCS would like to facilitate foreign small and

medium sized companies to explore business opportunities with a view to penetrating the market in China.

As far as we know, the demand of some quality products is high in China, e.g. operating room tables and operating lamps. Many of the newly-built operating rooms contain a full set of medical equipment manufactured by foreign companies. With the living standard increasing in China, more and more foreign quality products are widely used and accepted in the Chinese market.

I would like to thank President Wang Yao, the Chairman of CCCS, for his guidance in producing this paper.



Filling line of cough syrup, traditional Chinese medicine treating coughs

ASPEC Guideline on Isolator Qualifications

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1. INTRODUCTION

Isolators are devices that use a leak-tight physical barrier for separating a classified internal environment from an external environment and for separating a process from the personnel. Isolation technology can greatly contribute to controlling contamination. Isolators are becoming more and more widely used in the pharmaceutical industry, the hospital pharmacy, and the cosmetic and food and beverage industries. They are also used for aseptic production and microbiological testing.

ASPEC¹ has produced a Guide on Isolator Qualification, the objective of it being to answer the following question: How to qualify an isolator? This work mainly concerns isolators under positive pressure. It is written in English. The ASPEC guide should be used as a reference document by all professionals using isolation technology and should contribute to the improvement of health products.

2. QUALIFICATION STEPS

There are four steps to qualify an isolator: Design, installation, operational and performance qualifications.

2.1 Design Qualification (DQ)

The design qualification is the initial phase where the design and drawings are approved by the user.

The three successive steps are as follows:

1. the user defines his needs that are detailed in the user specifications,
2. the manufacturer answers by giving a functional specification,
3. the user approves the functional specifications.

At this stage of the project, it is recommended to check the layout and the functional specifications of the isolator with respect to the room, in particular for environmental safety reasons. The isolator, the room and the application mix must be checked for coherence, especially concerning ergonomics.

2.2 Installation Qualification (IQ)

The installation qualification is carried out on site; the isolator is not switched on. Installation qualification includes the following points:

2.2.1 Review of documentation provided by the supplier

- Description of the system, the qualification limits and the instructions for use
- List of equipment, drawings and test procedures
- Piping and instrumentation diagram
- User's manuals and procedures
- Preventive maintenance manual
- Sterilizing agent and material compatibility
- Summary of the materials and marking drawing (material certificates of conformity, documentation concerning the acceptance of basis material as per standards EN 10 204 and NF A 49 000)
- List with references and technical specification sheets of spare parts and consumables.

2.2.2 Verification of the conformity with the specifications

- Presence and identification of the elements
- Visual inspection of each element
- Dimensional and accessory check
- Certificates of conformity for each piece of equipment
- Calibration certificates
- Visual inspection of the connections including the connections of peripheral equipment
- Electric cable check
- Mechanical check of doors, half suits, sleeves, fluid connections and filter accesses
- Verification of the sterilizer connections
- Check of marking/identification of all the elements

At the end of the installation qualification, a report must be issued and signed by the project manager and the supplier for the tests that have been carried out.

2.3 Operational Qualifications (OQ)

Operational Qualifications may be carried out internally or be subcontracted to the supplier of the equipment or to an independent body. At the end of operational qualification, a report is issued. All test equipment used must be supplied with a calibration certification, or at least a valid verification report. The performances of the isolator are checked. The isolator operates under normal working conditions (ventilation running....), but in standby mode. The OQ tests are described in the ASPEC guide in the form of test sheets. These are as follows:

1. HEPA filter integrity test. The objective of this test is to check the integrity of the inlet and exhaust filters and, if applicable, the recirculation filters. Transport and assembly can affect filters performances; also it is necessary to test the integrity of the media, seals and assembly of the filter onto the isolator. The test is carried out preferably at nominal flow rate of the isolator ventilation system.

2. Leak testing of the enclosure. The objective of this test is to determine leak rate of the isolator “Lr” by pressure drop; “Lr” is the ratio between the leak rate of the enclosure under normal working conditions (pressure and temperature) and the volume of the enclosure.

3. Location of leaks. The objective of this test is to locate possible leaks by the ammonia method. This method is carried out using a NH₃ indicator cloth impregnated with bromophenol blue that turns from yellow to blue when in contact with ammonia.

4. Functional check of pressure regulation and alarms. The objective of this test is to evaluate the deviation between the values read directly on the manometers of the isolator and the values read on a reference manometer. This test can also be used to evaluate the correct operation of the isolator pressure regulation system if present: pressure regulation, opening/closing of the valves.

5. Verification of the program operating an isolator fitted with a computer. This test concerns isolators fitted with a computer. The objective of the test is to check that the correct version of the program(s) has been installed and to verify the conformity of each phase with the functional analysis referred to during the validation of the program.

6. Air change rate per hour. The air change rate per hour of the isolator (in V/h) is determined by the ratio of the inlet air flow rate divided by the volume of the isolator.

7. Air distribution studies. The objective of this test is to visualize the airflow in the isolator in order to find potential dead zones. The results of this test, performed under normal working conditions, are used to define the location of worst case measuring points (particle count, chemical indicators and inoculated carrier locations). The isolator is tested under two conditions (empty and loaded) and for two configurations (normal operation and sterilization mode).

8. Particle counting in the isolator. The objective of the test is to evaluate the concentrations of suspended particles in the isolator with a particle size distribution between 0.5 and 5 µm. This test checks the classification of the isolator at rest and in activity (when required by the application).

9. Sterilizer tests (for Peracetic Acid - PAA). The objective of the test is to check the repeatability of vapour production of the sterilizer inside an isolator during 3 cycles. The presence of sterilizing vapours in the isolator is checked by monitoring the following parameters: PAA heating temperature, flow rate and compressed air pressure, PAA consumption.

10. Sterilizer tests (for Hydrogen Peroxide - H₂O₂). The homogeneity of the temperature is an important parameter for sterilization by Hydrogen Peroxide (H₂O₂). The objective of the test is (i) to establish a detailed map of the surfaces temperatures inside the isolator during the sterilization cycle, (ii) to determine the coldest points and the warmest points inside the equipment and (iii) to check the distribution of H₂O₂ during sterilization by means of chemical indicators.

12. Empty micro-biological sterilization tests. The objective of the test is to check the efficiency of a surface sterilization cycle using inoculated carriers, each inoculated with 6 log of spores *Bacillus subtilis varians niger* ATCC 9372 (for PAA) or *Bacillus stearothermophilus* ATCC 7953 (for H₂O₂) distributed at distinct locations in the isolator.

13. Aeration test. The objective of the test is to determine, after a complete sterilization cycle, the aeration time required to obtain a residual concentration of the sterilizing agent compatible with the safety of operators and environment, and also compatible with the type of operations performed in the isolator. The isolator is set up ready for use.

14. Dynamic particulate decontamination (or recovery time) of the isolator. The objective of the test is to determine the capacity of the isolator to eliminate particles following an operation that has generated particles. The test consists of firstly artificially polluting the isolator (by stopping the ventilation system) so as to obtain a peak of particle concentration. The isolator is then restarted. The test consists of following the reduction of particle concentration over time.

15. Noise level (generated by the isolator in the room). The objective of the test is to check that the noise level generated by the isolator during operation is not too high for the operator.

16. Light level. This test ensures a maximum level suitable for comfort, when operations and manipulations are carried out by an operator.

2.4 Performance Qualifications (PQ)

Performance Qualification follows the writing-up, approval and implementation of operating procedures and protocols.

Performance Qualification requires training and qualification of personnel, who will be carrying out the performance qualifications tests and subsequently routine operation of the equipment. Performance Qualification is carried out during routine activity. The isolator must be fully equipped; the transfer isolator is loaded (with one or several loads). The operation criteria used are those determined during the operational qualification phase.

Examples of performance qualification tests are described in ASPEC Guide as test sheets. These are as follows:

- 1. Checking of procedures.** The objective of this test is to check that the procedures are present, and conform to the main isolator and additional equipment, for example, one (or several) transfer isolator(s), a product “transfer hatch” often integrated with the main isolator, inlet and outlet containers, waste containers.
- 2. Air distribution studies.** The objective of the test is to visualize the airflow in the isolator in order to find potential dead zones. This test is performed under normal working conditions with the load. Personnel are positioned at the work station in a half-suit, or using gloves.
- 3. Loaded micro-biological sterilization tests.** The objective of the test is to check the efficiency of a surface sterilization cycle using inoculated carriers, each inoculated with 6 log of spores *Bacillus subtilis varians niger* ATCC 9372 (for PAA) or *Bacillus stearothermophilus* ATCC 7953 (for H₂O₂) distributed at distinct locations in the isolator. The isolator has a load (loads) and has been tested in sterilization mode.
- 4. Checking for residual of the sterilizing agent in the load after sterilization.** The objective of the test is to check the residual quantity of the sterilizing agent in each vial or in other containers and to ensure that the residual levels do not affect the product. Check of residual concentration of the sterilizing agent is carried out using a semi-quantitative method with strips or using a quantitative method (e.g. HPLC).
- 5. Aeration test.** The objective of the test is to determine, after a complete sterilization cycle, the aeration time required to obtain a residual concentration of the sterilizing agent compatible with the safety of operators and environment, and also compatible with the type of operations performed in the isolator. The isolator has one load, or several loads, and is set up ready for use.
- 6. Check of the nutritive properties of the media.** The objective of the test is to check that the nutritive properties of the culture media used to test for sterility or environmental testing are not affected by the sterilization cycle or by the residues of the sterilizing agents used in the isolator.
- 7. Checking that sterility is maintained in the enclosure.** The objective of the test is to check that sterility and environmental conditions are maintained for a defined period during routine operation: 7 days minimum between cycles, or for a period during which sterility of the isolator is required.
- 8. Check of the bacteriostatic and fungistatic activity.** The objective of the test is to check the absence of false-negatives, i.e. to ensure that surface sterilization does not have an effect on the bacteriological and fungistatical activity on test samples to be sterility tested.
- 9. Sterility testing (for isolators intended for sterility testing).** This test is not compulsory; it is carried out when there is a change of method or equipment. The objective of this comparative test on a work station isolator is to ensure that the efficiency of sterility testing is not affected by the working conditions of an isolator. The test consists of comparing sterility testing in a work station isolator with sterility testing performed in a Class A room.
- 10. Media fill test for the work station isolator.** The objective of the test is to verify the integrity of the process and to check that sterility of the produced units is maintained.

3. CONCLUSION

The ASPEC Guide “Isolators Qualifications” is the result of an exchange of experiences and knowledge of a team from different fields specializing in isolation technology i.e. industrial pharmacists, hospital pharmacists, equipment suppliers and service providers. The Guide describes in a pragmatic and didactic way the current knowledge in this field. These guidelines list a series of procedures in the form of test sheets for the operational and performance qualification. The tests are compulsory or optional as a function of the type of surface sterilizing agent, hydrogen peroxide and peracetic acid. Control of contamination by isolation technology will contribute to the improvement of products if the various steps in qualifying the isolator have been carried out in the correct way.



- ¹ French Association for the Prevention and Study of Contamination
- ² International Confederation of Contamination Control Societies

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PD 6609: 2007 – Guide to in situ high efficiency filter leak testing

John Neiger, Consultant¹

Following the publication of BS EN ISO 1644-3: 2005: Test Methods, PD 6609 has been updated and will be published by BSi in the early part of 2007. As in previous editions, it will contain information that is supplementary to the most recent standards. In addition it will contain suggested templates for the specification of filters and the reporting of tests. Because the in situ leak test is not the same as the filter manufacturers' test, it is recommended that the in situ test is included in the specification when filters are ordered. The scope of PD 6609: 2007 is specific to filters that can be face scanned, i.e. cleanroom filters and filters in unidirectional airflow cabinets. There is therefore a need for an additional standard to cover the leak testing of filters in configurations that cannot be readily scanned such as are found in separative devices (BS EN ISO 14644-7: 2004) and microbiological safety cabinets (BS 12469: 2000). A proposal for such a standard has been put to BSi.

History

The first PD 6609 was published in 1996 as an explanatory supplement to BS 5295-1: 1989 and provided comprehensive supplementary information on filter testing. When BS EN ISO 14644-1: 1999: Classification of air cleanliness was published, BS 5295-1: 1989 was withdrawn. PD 6609: 2000 was therefore rewritten to carry forward not only the comprehensive supplementary information on filter testing, but also the filter test itself from BS 5295-1 as this had been 'lost' without being replaced in BS EN ISO 14644-1. There were additional sections on the measurement of pressure differentials and the measurement of particle contamination by sampling. The publication of BS EN ISO 14644-3: 2005 Test methods, meant that all these areas were now covered by the ISO standard. However LBI/30, the BSi committee responsible for cleanroom standards in the UK was not happy with this new ISO standard and especially with section B.6: Installed filter system leakage test. A proposal was therefore prepared and approved for a new issue of PD 6609.

Scope

It is worth dwelling on the Scope as this is a section that is often skipped over. The scope should specify what is covered by the standard and what is not. It is therefore a yardstick against which the content of the standard can be judged. Sometimes the scope of a standard can be over-ambitious and cover areas that are outside the expertise of the technical committee drafting it. One example of this is ISO 10648: Containment enclosures, which is written by nuclear experts and yet claims to cover sterile applications! In the case of PD 6609: 2007, the opposite is the case and the scope is both specific and narrow. The document provides recommendations and explanatory guidance for in situ leak testing of high efficiency filters using an oil aerosol challenge and photometer. The guidance is only for filters that can be face scanned.

Requirements for testing

A number of guidance points are given under five headings. Rather than list all of these, a selection of the more practical points under each heading is given here: -

- **Aerosol injection**

Sparge pipes may be used where the duct length is insufficient for good mixing.

Oil aerosol injection pumps may be required in positive ducts.

In negative ducts the photometer may be used in differential sampling mode, i.e. the photometer exhaust air is returned to the negative duct.

- **Aerosol challenge**

ISO 14644-3 states that the mass median particle diameter will typically be between 0.5 μm and 0.7 μm with a Geometric Standard Deviation (GSD) of up to 1.7. However a thermal generator is known to produce a smaller particle that is closer to the MPPS of high efficiency filters. Therefore more leaks may be found with a thermal generator. This is not considered a disadvantage.

The upstream concentration should be checked and recorded both at the start and upon completion of each filter scan.

- **System scanning**

It has been well established that linear photometers can readily measure penetrations down to 0.001%.

The sealing device, housing and filter are all subject to the test.

Slow scanning may improve sensitivity for finding leaks and fast scanning may miss leaks.

- **Airflow through filters**

Filter penetration varies with the airflow rate through the filter.

If the flow rate through the installed filter is higher than when tested by the filter manufacturer, the penetration may increase to a point where it gives an in situ test failure.

- **Repair of filters**

An effective repair at the gasket, and between the filter pack and frame, can often be achieved but the repair of media leaks is difficult to achieve and, because of blockage, may have adverse effects on the uniformity of airflow.

In a non-unidirectional cleanroom the air supply will quickly mix with room air and a less than perfect repair can be tolerated.

• **Repair of filters *continued***

In a unidirectional cleanroom, especially if the air is supplied directly to a critical area, the filter would normally be renewed. Where temporary repairs are made to allow vital work to continue, a replacement filter needs to be installed as soon as possible.

Annex A; High efficiency filter specification table

Annex A explains the leak tests carried out by the filter manufacturer, the difference between these and the in situ leak test (as described in BS EN ISO 14644-3: B.6 and PD 6609) that is carried out on installed filters, and why this in situ test must be specified at the time the filters are ordered. The table in Annex A is a template for a detailed specification under the following headings: -

Application information	Location, function, temperature, RH, removal method, disposal method, manufacturers' name and designation
Airflow	Non-unidirectional flow/unidirectional flow, airflow, uniformity, initial Δp
Manufacturers' filter test method	EN 1822, Eurovent 4/4 (BS 3928), Manufacturers' leak test scan
In situ leak test to be carried out on installed filter	Leak test method, aerosol type, % penetration
Filter mechanical specification	Dimensions, knife edge seal details, frame material, gasket, airflow laminator, mesh guard, separator, media, construction
Drawing to show dimensions	* Height x Width x Depth

* The convention is for height and width to define the dimensions of the face area of the filter, where the pleats are in the vertical or 'height' direction, and for depth to define the dimension in the direction of airflow. (Filters should be stored and transported in the vertical orientation to minimise damage).

Annex B: In situ leak test report

Annex B. lists the information to be included in the in situ leak test report. The table in Annex B is a detailed template for a full test report.

Other filter configurations

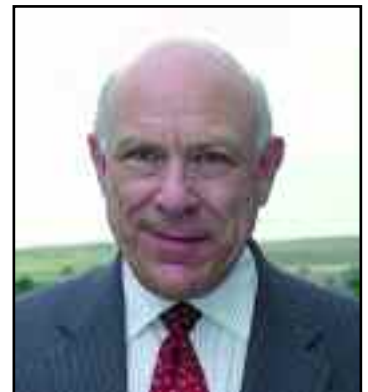
The scope of PD 6609: 2007 is restricted to the leak testing of high efficiency filters that can be faced scanned, and there is a further requirement for access to measure the upstream aerosol challenge concentration. There are a large number of clean air and containment devices built to BS EN ISO 14644-7: 2004 - Separative devices (isolators) and BS EN 12469: 2000 - Microbiological safety cabinets with 'difficult' filter configurations that do not allow one or other of these requirements to be met. Such devices therefore fall outside the scope of PD 6609: 2007, and indeed the earlier editions. For this reason a proposal has been submitted to BSi for a new standard to cover these situations which include: -

- Ducted exhaust filters
- Dual in line filters
- Filters where there is no upstream access for measuring the challenge
- Filters where the aerosol challenge cannot be applied with system running
- Filters, such as cartridge filters and multi-V filters, where a downstream scan in accordance with PD 6609 is not possible
- Filters with no immediate access for a downstream scan

BSi has invited the author of this article to be project leader for this new standard if it goes ahead, therefore comments and suggestions from readers would be very welcome.

¹ John was a founding director of Envair in 1972 and later chairman until 2004. His interest in clean air and containment technology continues with his membership of BSi LBI/30 and other technical committees, and with technical writing in this as well as in other fields. Good technical writing should be simple, unambiguous and precise in its use of terminology.

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CLEANROOM TESTING COURSES



A one day course on Cleanroom Testing is being given at Glasgow University, Glasgow
Wednesday, June 27, 2007

Course with hands-on demonstrations is given by Bill Whyte

Eligibility: Anyone: cleanroom *designers, users* or *personnel* responsible for testing and monitoring.

Cost: per delegate is £160 + VAT (£188.00) members and £177 + VAT (£207.97) for non-members.

Registration: Contact S2C2 office to obtain a course brochure and application form.



The Cleanroom Testing and Certification Board, is concurrently running a certification course in Cleanroom Testing which runs over 3 days, i.e. June 26-28, 2007 (and while the above one day course is being held).

Eligibility: People who test cleanrooms daily or regularly. There are 2 levels: Professional or Associate.

Cost: Registration is £110 + VAT. This covers the course and Question and Answer manuals. The course fee for Professional candidates is £616 + VAT and for Associate candidates is £440 + VAT.

Registration: To attend the course, registration is essential as candidate suitability is assessed.

CONTACT: Kay Johnston, Administrator, James Watt Building, Glasgow University, Glasgow, G12 8QQ, Scotland
Tel: 0141 330 3699 Fax: 0141 330 3501
E-mail: s2c2@mech.gla.ac.uk

Payment: Credit card facilities are now available on the web at www.s2c2.org/shop.

CTCB link is
www.s2c2.co.uk/ctcb/ctcb2

BASSAIRE ACQUISITION OF ENVAIR

Bassaire Limited is very pleased to announce its recent acquisition of Envair. This is exciting news for the Bassaire Group, which is the longest established cleanroom construction and clean air product company in the UK. Its products are now complemented by Envair's extensive and well respected product range and well established after sales and service department. All essential Envair staff including service and technical have been retained on the existing site. The acquisition will give clients of both companies one of the most comprehensive turnkey services available in the UK. Contact details and more information can be found on www.bassaire.co.uk and www.envair.co.uk. Both these websites will be updated shortly.

OFFGASSING OF FLOORING

Dear Sir,

I am writing in response to your article in *The Cleanroom Monitor*, Issue 56, [page4], October 2006.

As members of the Scottish Society for Contamination Control, and a major supplier of PVC vinyl flooring to cleanroom applications, we were troubled to discover your recommendation to avoid the use of this type of flooring on the grounds of chemical contamination due to offgassing. It is a popular misconception that PVC contains high levels of VOCs. Modern vinyl floorcoverings are formulated for ultra low emissions and compare very favourably to other resilient floor surfaces.

Indoor air quality within buildings is not a new concern and is not just pertinent to clean room use. Test methods, such as the FLEC (Field and Laboratory Emission Cell) and the German AgBB test, have been developed and widely used in Europe to measure atmospheric pollutants which may be emitted by a variety of sources. A European standard for floorcoverings, (prEN15052) is currently under development, based on the German AgBB test method. This measures both quantity and toxicity of emissions based on LCI values (Lowest Concentration of Interest).

To give an example of the performance of vinyl floorcoverings, Polyflor Prestige PUR is certified as having an R value after 28 days of 0.03 when tested in accordance to the AgBB-scheme. This extremely low VOC result is actually 97% less than the limit allowed for use in enclosed building spaces. Few resilient floorcoverings can claim such low VOC results. Contrary to your article, phthalates are not detected and therefore do not pose a hazard to clean room operation, and this has resulted in their successful use for many years.

Vinyl has many additional performance qualities ideally suited to clean room use. It is easy to clean, durable and can be used on all surfaces - floors, walls, and ceilings - and welded to form a continuous, impervious surface for cleanroom use. We hope that this information can be passed onto your readers to ensure decisions can be made on a scientific and informed basis.

Yours faithfully,

John G Kay, Group Technical Director,

James Halstead plc, Beechfield, Hollinhurst Road, Radcliffe, Manchester, M26 1JN

