

S2C2

THE CLEANROOM MONITOR

The Scottish Society for Contamination Control

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Issue 55

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Kay Johnston, Administrator (centre) at the 3C Contamination Control and Cleanroom Products event at the NEC Birmingham, February 15-16, 2006.

People visiting the stand were given information on courses in Cleanroom Technology and Cleanroom Testing run by the CTCB (Cleanroom Training and Certification Board) and were able to order or purchase the ISO standards.

Also on sale were Bill Whyte's two cleanroom books: *Cleanroom Technology* and *Cleanroom Design*.

Two cleanroom educational courses were run over the 2 day event: Cleanroom Technology and Cleanroom Testing. Attendance continues to be at the level of previous years with 68 people attending the one day course on Cleanroom Technology and 59 attending the one day course on Cleanroom Testing. While most delegates were from the UK there were several attending from Malaysia and one from Lebanon.

HARMONISATION of EC GMP ANNEX 1 with the ISO 14644 SERIES OF INTERNATIONAL STANDARDS

John Neiger, Consultant, Envair Limited and Technical Writer, March 2006

Environmental classification table for particles

On 29 July 2003 the UK Parenteral Society arranged a meeting with EMEA (the European Medicines Agency) to discuss the recently published revision of EC GMP Annex 1, Manufacture of Sterile Medicinal Products. There was a full house, with well over 100 delegates present, all clamouring to make their points, almost every one of which concerned the apparent disregard and misunderstanding of the international cleanroom standard, ISO 14644 Part 1:1999. By contrast, when The Scottish Society of Contamination Control arranged a technical forum in November 2004 for a discussion on possible changes to 14644-1, which was then up for review, the meeting was cancelled due to lack of interest. It was therefore very clear that practitioners had far greater concerns about the application of Annex 1 of the EC GMP than they did about 14644-1!

In September 2005, in response to the representations made at the Parenteral Society meeting and elsewhere, EMEA issued 'GMP Annex 1: Proposals for amendment to the environmental classification table for particles and associated text...' for public comment. Unfortunately, these new proposals still fall a long way short of harmonising the environmental classification table for particles with that of 14644-1, and still fail to recognise the limitations and practicalities of air sampling of very small particle concentrations.

The Annex 1 definitions of air cleanliness grades, from Grade A (cleanest) down to Grade D, continue to differ from those in ISO 14644-1. For particles that are 0.5µm in size or greater, the difference is so insignificant that Annex 1 could easily have adopted the ISO figure for consistency. Grade A allows a maximum concentration of 3,500 per m³, compared with 3,520 in ISO class 5, which is the nearest equivalent, ISO class.

For particles that are 5µm in size or greater, the difference is significant, with significant implications. Annex 1 allows a maximum of 1 such particle per m³ (for Grade A 'at rest' and 'in operation' and Grade B 'at rest'), whereas ISO class 5 allows 29. EN ISO 14644-1 (B.4.2.1, equation B.2) specifies that the single sample volume should be such that a 'minimum of 20 particles would be detected if the particle concentration for the largest considered particle size were at the class limit for the designated ISO class'. This is to ensure that the sample is statistically significant. Therefore, for a maximum particle concentration of 1 per m³, the sample volume would need to be 20 m³!

The statement in the EMEA proposals that a 1m³ sample size will give rise to a sampling time of 35 minutes is correct but irrelevant, because that size of sample is 1/20 of what it needs to be to satisfy 14644-1 (and to be statistically significant).

It is the author's opinion that this problem stems from early airborne particulate classifications, such as US Federal Standard 209, being in imperial units (cubic feet). For example Federal Standard 209 class 100 has a maximum concentration of 100 0.5µm particles per cubic foot.

Most particle counters currently in use sample at the rate of one cubic foot per minute, as they were developed to operate in conjunction with this standard. One cubic foot per minute is 0.0284 m³ per minute or 28.4 litres per minute.

A class limit of 1 per ft³ (or 35 per m³) for 5µm particles is perfectly practical to sample, as the single sample volume would be 1m³, and near enough the class limit of 29 per m³ of ISO 5. Particle counts at 5µm of >1 per cubic foot (i.e. >1 per minute) should be an entirely adequate 'indicator of a possible contamination event' with any more stringent specification producing 'false counts due to electronic noise, stray light, coincidence etc'.

It is therefore the author's recommendation that EMEA adopts EN ISO 14644-1 in full and accepts the expertise and knowledge of those who formulated this generic standard.

The table for the maximum permitted airborne particle concentration for each grade could then be shown as follows (two alternatives):

Alternative A:

particles per m³ correspond precisely to those in the equivalent classes in EN ISO 14644-1:1999

Grade	at rest		operational [*]	
	0.5µm	5µm	0.5µm	5µm
A	3520	29	3520	29
B	3520	29	352000	2930
C	352000	2930	3520000	29300
D	3520000	29300	not defined	not defined

^{*} 'Operational' is defined in EN ISO 14644-1:1999 as 'condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon'.

HARMONISATION OF EC GMP ANNEX 1 continued

Alternative B:

particle concentrations are expressed as ISO Classes

	at rest	operational*
Grade	ISO Class measured at 0.5µm and 5µm	
A	ISO Class 5	ISO Class 5
B	ISO Class 5	ISO Class 7
C	ISO Class 7	ISO Class 8
D	ISO Class 8	Not defined

* 'Operational' is defined in EN ISO 14644-1:1999 as 'condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon'.

The covering text headed Cleanroom and clean air device classification could read:

Cleanrooms and clean air devices should be classified and monitored in accordance with EN ISO 14644-1:1999. Classification to demonstrate continued compliance with the assigned cleanliness classifications should be carried out at periodic intervals defined in EN ISO 14644-2: 2000. Monitoring on the other hand should be continuous or frequent (see clause 5). [Clause 5 in the EMEA Proposals covers monitoring].

Unidirectional airflow and laminar airflow in isolators

There appears to be confusion in the use of the terms 'laminar airflow' and 'unidirectional airflow'. The former term is no longer used in clean air technology and has an entirely different meaning in other branches of engineering and science.

The correct term is '**unidirectional airflow**', which is very well defined in EN ISO 14644-4:2001 as '**controlled airflow through the entire cross section of a clean zone with a steady velocity and approximately parallel streamlines**. **NOTE: This type of airflow results in a directed transport of particles from the clean zone**'.

In its definition of Grade A, EC GMP Annex 1 states that 'laminar air flow systems should provide a homogeneous air speed in a range of 0.36 – 0.54 m/s (guidance value) at the working position in open clean room applications'. It then goes on to say that 'a unidirectional air flow and lower velocities may be used in closed isolators and glove boxes'.

Putting to one side the misuse of the term 'laminar air flow', the concept of lower airflow velocities being effective inside unidirectional airflow isolators might seem to be a reasonable intuitive conjecture. The author therefore carried out a series of tests inside a unidirectional airflow isolator to verify this and, to the author's own surprise, these showed very clearly that velocities lower than those given in this Annex are less effective in providing the 'directed transport of particles from the clean zone'. A video (on CD) of these tests is available from the author.

The author would therefore propose the following wording for the definition of Grade A in Annex 1:

Grade A: The local zone for high risk operations, e.g. filling zone, stopper bowls, open ampoules and vials, making aseptic connections. Normally such conditions are provided by a unidirectional airflow work station. Unidirectional airflow systems should provide a homogeneous air speed in the range 0.36 – 0.54 m/s (guidance value) at the working position both in open cleanroom applications and in closed isolators and glove boxes wherever a directed transport of particles from the clean zone is required.

Uniformity of airflow velocity should be demonstrated and validated for all unidirectional airflow systems.

(The last sentence of the existing definition 'A unidirectional air flow and lower velocities may be used in closed isolators and glove boxes' should be deleted). Please note that the proposed wording does not in any way preclude the use of turbulent or 'non-unidirectional airflow' isolators or glove boxes (which work by the dilution of process generated airborne contamination). Such isolators are recognised in the last sentence of the section headed **Isolator technology**.



For further information:

e-mail: jneiger@johnwrite.co.uk

internet: www.johnwrite.co.uk

Also refer to page 5 column 1.

REVISION OF ISO 14644-1 and ISO 14644-2

Both the ISO 14644-1 and the ISO 14644-2 have been published for over 5 years. It was decided at the meeting in Moscow, in September 2005, of the main committee (TC209) that the work group (WG1), which writes these two standards, should proceed with the revision. For a summary of the Moscow meeting see the report by Bill Whyte on page 7 of *The Cleanroom Monitor*, Issue 54, October 2005.

WG1 met in Woodfield, near Chicago, on the 11th and 12th November, 2005 to consider what revisions might be necessary. Eight countries were represented - Japan, Germany, France, Italy, USA, Sweden, France and the UK. The Secretariat of this committee is held by the UK and the chair was Gordon Farquharson, and the UK expert was Mike Foster who is a S2C2-nominated expert on the BSI committee.

General consensus was achieved on all points raised and discussed. These possible changes to the standards are as follows.

Revision of ISO 14644-1

Sample locations

It was agreed to consider whether the algorithm requires to be changed to make the sample locations dependent on the cleanliness classification.

95% Upper Confidence limits (UCL)

In the present standard, the 95% UCL must be calculated when the samples taken in the cleanroom are less than 10. This statistical test ensures that the variation found in a small sample will not cause the cleanroom to fail when a larger sample is taken. Doubts have been expressed about the use of the 95%. WG1 was fortunate to have the assistance of Dr Mark Varney, a statistician who has been practicing in the cleanroom environment for the past 28 years.

After much discussion, the group realised that this section was to be the subject of a sub-group homework project in order to revise Annex B and form an elegant solution.

Classification table

Classification will now be by the classification table, with the formula only being used (one way) to determine decimal classifications (e.g. ISO Class 3.5). The log/log diagram will be replaced with one that has a better presentation and more detail, and reflect the new class limits explained below.

It was agreed that the limits from the classification table were too small for reliable and repeatable classification and encourage bad practice. The ISO Class 5 count of particles $\geq 5 \mu\text{m}$ of 29 would be removed. Also removed would be the count of 8 limit in ISO 3; the 4 and 10 limits in ISO 2; and the 2 limit in ISO 1.

The Annexes

Annex B notes will be modified for clarity but the equations will remain. From the statistical information now to hand it will be necessary, in the light of recent observations, to

review the sampling procedure. Annex C will not remain in its present form. Annex F, which covers sequential sampling, will be given in a more understandable and workable form.

Revision of ISO 14644-2

The ISO 14644-2 revision needs to reflect the more recently published parts of the cleanrooms standards. It was noted that in practice some tests are not undertaken by all cleanroom users and in some cases are never repeated.

It was decided that the various tests for classification and monitoring will be better presented and thus it will make a more useful document.

Finalising the Documentation

The time frame for a new version of both of these documents is approximately 3 years, if all matters proceed well through the ISO and CEN procedures.

It is expected that only one or two further meetings of WG1 will be required as most of the identified work will be undertaken through emails. All in all, the result will be a more succinct and practical document.

Mike Foster



S2C2 stand at the 3C Exhibition in Birmingham

REVISION TO ANNEX 1 of the EU GGMP

The latest revision of Annex I of the EU GGMP was released for comment on the 27/11/05 by the European Medicines Agency.

The proposed changes are controversial and people are reminded that comments are invited, and the final date for submissions is the 30 April 2006.

The document and other information is available at: <http://www.emea.eu.int/Inspections/WhatsNew.html>.

This reference states:

23.11.05 Good Manufacturing Practice

The European Commission is consulting on a proposed revision of Annex 1 of the Community GMP Guide. Annex 1 of the EC Guide to Good Manufacturing Practice (GMP) provides supplementary guidance on the application of the principles and guidelines of GMP to sterile medicinal products. In May 2003 following a review in the light of the international standard EN/ISO 14644-1 a revision was published with amendments the table providing recommendations on standards of environmental cleanliness for clean rooms. Further work has subsequently been carried out on this part of the annex. At the same time the need for a number of other minor changes to the annex were identified. It was originally envisaged that this work would progress in two separate stages however it has become possible to consolidate these changes and release them for public consultation simultaneously.

The proposed changes are:

- * A clearer text associated with the environmental classification table in section 3 and 4 of the existing annex.
- * Media simulation acceptance criteria in section 42 of the existing annex to be harmonised with the requirements of the FDA.
- * To provide guidance on the frequency of pre-sterilisation bioburden monitoring in section 52 of the existing annex.
- * To provide improved guidance on the appropriate environmental conditions for the handling of freeze-dried vials between partial stoppering and final sealing in section 88 of the annex.

The proposals can be found by clicking here. Comments are invited on these proposals and should be sent to

Sabine.Atzor@cec.eu.int

and

David.Cockburn@emea.eu.int

before 30 April 2006.

ISO 14644 - PART 3 TEST METHODS

Now available for purchase (see below) this standard covers:

Scope: (as quoted in the standard)

“This part of ISO 14644 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones.

Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational.

The test methods recommend test apparatus and test procedures for determining performance parameters.

Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested.

For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations.

Alternative methods not included in this part of ISO 14644 may be used if based on agreement between customer and supplier.

Alternative methods do not necessarily provide equivalent measurements.”

Contents: (as quoted in the standard)

1. Airborne particle measurement
2. Air filters and systems
3. Airflow and other physical states
4. Electrostatic measurement
5. Measuring apparatus and measuring conditions
6. Occupancy states
7. Test procedures:
 - Cleanroom tests
 - Principle
8. Test reports.

Annex A Choice of recommended tests of an installation and the sequence in which to carry them out.

Annex B Test methods

Annex C Test apparatus

To purchase a copy of this standard go to the S2C2 website:

www.s2c2.co.uk/merchandise/#iso

ISO standards are available for purchase through S2C2.

A discounted price of £126.00 is given to members.

To the public it is £140.00.

AIR SUPPLY VOLUME INACCURACIES

Measuring Air Supply Volume

The cleanliness of cleanrooms is directly dependent on the volume of clean air supply to the room. Three methods of measuring air supply volumes are used, these being the Pitot static, anemometer and hood method. The Pitot static method is universally considered to give the most accurate result but is a difficult and time consuming method, and little used when cleanrooms are routinely tested. There has been anecdotal evidence for some years that these three methods do not give the same result, and that the results from the different methods could differ by over 50%.

The Cleanroom Testing and Certification Board (CTCB) of S2C2 teach and examine engineers on their ability to certify cleanrooms. As part of this course, practical teaching is carried out on a test rig and the measurement of the air volume supplied through a HEPA filter using the three methods.

Measurements from the CTCB Rig

The air volumes coming from a HEPA filter were measured using the CTCB rig.



Air volume measuring rig with hood shown on the right

This rig is routinely used by 4 separate groups of students. The volumes were measured using the following methods:

1. Pitot static tube,
2. Anemometer,
3. Hood.

1. Pitot Static Measurement

Velocities were measured by a Pitot static tube over the cross section of the duct and the average velocity calculated. It should be noted for maximum accuracy the velocities were averaged rather than the velocity pressure. The cross sectional area of the duct was 25 cm, and a 6-point traverse was used. Three lines of traverse were taken across the duct, at 60° to each other and the velocities measured and

averaged. The area of duct was calculated and the air supply volume ascertained.

2. Measure of Air Volume with a Hood

A hood of the type shown below was used to measure the air volume coming from the filter face of the fan-filter unit.

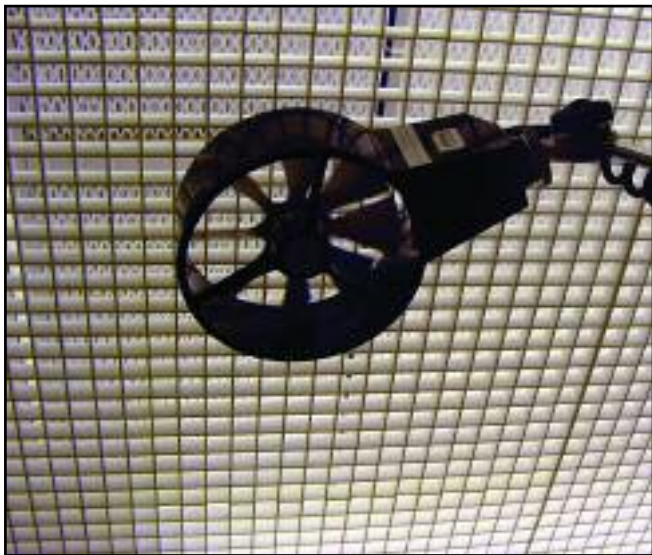


Hood being used to measure air volume coming from an air supply diffuser

3. Measurement of Air Volume Using an Anemometer

Air velocities were measured at 16 evenly distributed points over the filter. The velocity was measured using a vane anemometer at a distance greater than 10 cm away from the face and less than 20 cm. The filter face media area, not including the frame, was calculated and the air supply volume calculated as follows:

$$\text{Average air velocity (m/s)} \times \text{filter cross sectional area (m}^2\text{)} = \text{air supply volume (m}^3\text{/s)}$$



Anemometer

AIR SUPPLY VOLUME cont'd

Results

Results were obtained by 4 groups of people. These were as follows:

Type of Measurement	Group 1	Group 2	Group 3	Group 4	Averages
Pitot static tube	0.206	0.215	0.204	0.206	0.208
Anemometer velocity	0.26	0.261	0.292	0.294	0.277
Hood	0.191	0.188	0.190	0.189	0.190

These results were from a one day practical course. However, similar results have been obtained in other courses in the UK and Ireland when using different makes of anemometers and hoods. It was always found that, compared to Pitot static measurements, the anemometer method gave high results and the hood method gave low results. The average figures were usually about 15-20% higher for the anemometer method and 15-20% lower for the hood. This difference could lead to the air supply volumes in a cleanroom being 40% different, depending on the method used. This is unacceptable.

S2C2 is to Back University Research

S2C2 has agreed to contribute to a student project on this problem. It will be carried out at the Department of Mechanical Engineering at Glasgow University and supervised by Dr Whyte and Dr Green. It is hoped that further information on the problem of measuring air volumes in cleanrooms will be given in further editions of this newsletter.

SCOTTISH SOCIETY FOR CONTAMINATION CONTROL

Members Directory

This publication is to be discontinued therefore there will be no 2005-2006 edition.

CLEANROOM COURSE

The next Cleanroom Technology course is

Thursday 26th October, 2006

Erskine Bridge Hotel,
Erskine, Near Glasgow

(The S2C2 AGM will also be held at this time.)

The Cost

Price per delegate including lunch and tea/coffee:

Members: £160 (£188 incl. VAT)

Non-members: £177 (£207.98 incl. VAT)

Exhibitors

Exhibitors are invited to attend this meeting.

The cost will be £200 (£235 incl. VAT) for a tabletop exhibition.

Further Information

- [1] There is a course manual which comes with the course - a valuable reference aid.
- [2] A copy of the book *Cleanroom Technology - Design, Testing and Operation* can be ordered at an additional discounted price of £58.50.
- [3] A CTCB Certificate in Cleanroom Technology can be obtained by sitting a written exam after the course. Further details are available from S2C2.
- [4] To pay by credit card go to

www.s2c2.org/shop

or make cheques payable to Scottish Society for Contamination Control and forward with the remittance form to:

Kay Johnston,
S2C2, James Watt Building,
Glasgow University,
Glasgow, G12 8QQ.

Tel: 0141 330 3699

Fax: 0141 330 3501

Email: s2c2@mech.gla.ac.uk

CLEANROOM TESTING COURSES



A one day course on Cleanroom Testing is being given at Glasgow University, Glasgow
Wednesday, June 28, 2006 (Registration 8:30 - 9:00 am)

Course given by Bill Whyte includes hands-on demonstrations of equipment used to test a cleanroom.

Cost: per delegate including lunch and tea/coffee is

Members: £160 + VAT (£188.00) Non-members: £177 + VAT (£207.97)



While the above one day course is being held, the Cleanroom Testing and Certification Board, (a body set up to run courses for people in the cleanroom industry) is concurrently running a certification course in Cleanroom Testing which runs over 3 days, i.e. June 27-29, 2006.

Course Options: If you wish to attend any of these courses see below,

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

If you want CTCB certification then it is the 3 day CTCB course

Registration

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

Eligibility

This course is for people who test cleanrooms either 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 is £616 + VAT which includes a one day practical training course.

Examinations

Two - theory and practical.

Certification

On successfully passing both exams a certificate is awarded.

If you do not want CTCB certification then it is the 1 day S2C2 course

Registration

Contact S2C2 office to obtain a course brochure and application form or use the application form on page 9.

Eligibility

This course is for anyone. For example, cleanroom *designers* who need to understand the standards and the tests to which their cleanroom is tested, *users* who have to understand what tests are required or *personnel* responsible for testing and monitoring cleanrooms.

Cost

Members: £160 + VAT (£188.00)
Non-members are required to pay an additional £17 + VAT. See above for June 28, 2006.

Examinations

None.

Certification

A certificate of attendance is issued.

For further information:

Mrs 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

www.s2c2.co.uk and click on 'CTCB' and then 'Cleanroom Testing'

Cleanroom Testing Courses, Glasgow University, June 28, 2006

Over the past few years S2C2 have run a successful course on how to test a cleanroom. Owing to the needs of the Cleanroom Testing and Certification course of S2C2, that course has now been expanded.

Who Should Take This Course?

- Cleanroom designers who need to understand the standards to which their cleanroom is tested.
- Cleanroom users who have to understand what tests are required to ensure that their room continues to perform as required.
- Personnel responsible for testing and monitoring cleanrooms.

Why? As an introduction to new technology or to brush up knowledge and skills.

MORNING - LECTURE

08.30 - 09.00 Registration
 09.00 - 13.00 Lecture Course given by Bill Whyte

Topics include:

- The reasons for validating a cleanroom
- Validation philosophy • Validation standards
- How a cleanroom air conditioning plant works
- Cleanroom conduct • Microbiological measurements
- Air volumes and velocities
- Differential pressures • Air filter integrity test
- Infiltration of contamination into the cleanroom
- Particle measuring methods according to ISO 14644-1

AFTERNOON - PRACTICAL

13.00 - 14.30 Lunch
 14.30 - 16.30 Practical Demonstrations

In this session a 'hands-on' demonstration of equipment used to test a cleanroom will include:

- Instruments for measuring air velocity, volume & pressure differential
- Filter integrity testing method
- Particle counting apparatus
- Bacterial counting apparatus
- Air movement visualisation methods

COST

Price per delegate including lunch and tea/coffee is £188 (£160 + VAT)
 Non-members will be required to pay an additional £19.98 (£17 + VAT)

PAYMENT

[1] Credit card: go to www.s2c2.org/shop
 [2] Cheque for £attached
 Please make cheque payable to *Scottish Society for Contamination Control* and forward with this remittance form to
 S2C2, James Watt Building,
 University of Glasgow,
 Glasgow G12 8QQ.

CONTACT

Tel: 0141 330 3699 Fax: 0141 330 3501
 Email: s2c2@mech.gla.ac.uk

APPLICATION FORM

Please reserve places for the following people:

	Company:	Tel:
	Address:	Email:
Send invoice to (if different from above):		Purchase Order No.

CLEANROOM WEBSITE

What's What and Who's Who:

If you want to connect with cleanroom people try the internet.

All topics pertaining to cleanroom issues are found on the one website which is run and monitored by The Scottish Society for Contamination Control.

The site is divided into 2 categories:

[1] www.S2C2.co.uk

This section covers general notices, standards, courses, products and services, and provides a shop for the purchases of books, standards and course material.

[2] www.S2C2.org

This section covers the question and answer 'bulletin board' site called *The Forum*. This is the International Confederation of Contamination Control Societies' site and, as such, is the only global service (both in essence and function) in existence.

Therefore, although the operation of the site is based in the UK, the uptake is very much global - quite literally every country in the world enters through its 'net-doors'.

Current trends:

[1] www.S2C2.co.uk section

(1) Most people who come on to this site are looking for Products and Services. For example, there were 4,273 hits in the 5 month period of October 2005 to February 2006 ... clear evidence that it pays to advertise.

For further information about advertising on the website please contact the S2C2 office at s2c2@mech.gla.ac.uk.

(2) The next most popular topic is Documents and Standards. The new ISO standards relating to cleanrooms are now available for sale from the shop on the website. (If you are a member of S2C2 you get them at a reduced rate.)

(3) During the months of October 2005 - February 2006 one particular topic which scored a large number of hits was for an article in the S2C2 12 page newsletter *The Cleanroom Monitor*, Issue 36, February 1999, pages 1, 3-5, "Cleanroom Clothing Performance" by Robin Howie.

(4) All course enquiries are up on last year and the bookings are being sent in earlier. For example, interest is already being shown for a Cleanroom Technology course scheduled for October 26, 2006 at Erskine, near Glasgow.

[2] www.S2C2.org section

(1) There are 950 users registered on The International Forum.

(2) Average number of hits per day from October 2005 to February 2006 was 1, 221.

The International Forum:

This is where topics are posted and discussion takes place. Some examples of topics covered are:

[1] *Air Shower Studies or Articles*

I recently was hired on to a aerospace project. We have multiple cleanrooms, some with airshowers and some without. I do not believe in airshowers, beyond the two interlocking doors. The high energy air is worthless in my view. But I need to justify this with our customer. Anybody have data or articles relating to the use of airshowers? [DK]

[2] *Use of Face Masks*

During a recent visit to my supplier class 100 clean room, I noticed that they do not wear a face mask. Instead, it is a one piece hood that covers the most of the head leaving only the area around the eyes. The hood is used for 3 days before they are changed. Will there be contamination concern? [C]

[3] *Cleaning in Clean Room*

I've a question about cleaning tools in the cleanroom. Our cleanroom is running 24hours a day. So I arrange floor cleaning once per 12 hours. The question comes with the cleaning tool used, like vacuum cleaner, flat mop, detergent. Should these tools be stored inside cleanroom or placed in buffer zone, like pre-entry room, but take into cleanroom every time they're going to be used? I prefer first one. Any one could suggest what kind of storage I should make? [M]

[4] *Cleanroom Microbiological Monitoring*

At the present time we are using 2 types of agar medium for Cleanroom Microbiological Monitoring: Tryptic Soy Agar and Sabouraud Dextrose Agar. We would like to know if it is enough to use only the Tryptic Soy Agar, incubating the same plate at different temperatures (7 days at 20-25°C and then 7 days at 30-35°C) to get bacterial, fungi and yeasts colonies. [MQ]

[5] *ESD Control in Cleanroom*

I work in factory that makes lens for digital cameras. We have Class 5,000 cleanroom. But we have many dust on our lens. We are looking for getting rid of this. Someone say less problem of cleanroom, more of ESD. How can I fix this? [K]

[6] *Particle Fallout*

I work in an ISO-7 Class aerospace cleanroom where particle fallout is a concern. Does anyone have experience relating air cleanliness classes to particle fallout (MIL-STD-1246)? [DB]

[7] *Sampling Concentrated Air Flow*

I have a 10' duct that flows HEPA filtered air between 50 and 160 lbs/min into my Class 7 cleanroom. I need to be able to have an accurate particle count, but am having trouble figuring out how to do this with my existing 1.0 cfm particle counters. [M]

[8] *Monitoring a Cleanroom*

Is it necessary to perform particle counting, active air sampling, swab testing daily? [SK]

NEC



It was standing room only at the free show-floor presentations during the 3C Contamination Control and Cleanroom Products event at the NEC in February 2006. Shown here is David Hague of Bassaire Projects giving a presentation on Cleanroom Design and Construction : a Client's Perspective.

DUBLIN 2006

*Training Seminar*

Dublin, September 12-14, 2006
(part of the first Pharmatex Exhibition)

BEIJING 2006

**The 18th International Symposium on
Contamination Control & China
International Exhibition on
Contamination Control 2006**

September 6th ~ 7th, 2006

The Military Museum of China, Beijing

AT YOUR SERVICE

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