

S2C2








THE CLEANROOM

# MONITOR

## The Scottish Society for Contamination Control

November 2004

Issue 51

-  ICCCS
-  WEBSITE
-  COURSE
-  HOSPITALS
-  BRUSSELS
-  ISOLATORS
-  CLOTHING

**Co-ordinates:**

Mrs Kay Johnston,  
Administrator,  
James Watt Bldg,  
Glasgow University,  
Glasgow, G12 8QQ  
Scotland

Tel:  
0141 330 3699

Fax:  
0141 330 3501

E-mail:  
s2c2@mech.gla.ac.uk

Website:  
www.s2c2.co.uk



## HONORARY LIFE MEMBERSHIP FOR LYNN MORRISON

At the Annual General Meeting of S2C2 on October 27, 2004 Bill Whyte (right) presented outgoing Chairman Lynn Morrison with the crystal award which reads

Honorary Life Membership

Presented to Lynn Morrison

In recognition of an outstanding contribution to Cleanroom Technology

Presenting her flowers is Andrew Tweedie (left) of Andersen Caledonia Ltd, Strathclyde Business Park, Glasgow, the new Chairman of the Society.

**ICCCS 2004**

**ICCCS Meets in Bonn September 2004**

The Council of Delegates of the International Confederation of Contamination Control (ICCCS) met in Bonn, Germany on September 8th, on the occasion of the ICCCS Symposium, and under the Chairmanship of Dr. L Gail. S2C2 was represented and there were also delegates from the cleanroom societies of

- ASCCA/Italy
- ASENMCO/Russia
- CCCS/People's Republic of China
- GAA-RR/Germany
- ICS/Ireland
- IEST/United States
- JACA/Japan
- KACRA/Republic of Korea
- R3-Nordic/Denmark Finland, Norway, Sweden
- SBCC/Brazil
- SRRT/Switzerland
- VCCN/Netherlands

There were apologies for absence from ASPEC/France, ARCC/Romania and BCW/Belgium. The Society for Environmental Engineers from the UK did not attend the meeting as they had decided to terminate their membership of ICCCS.

**Papers Submitted**

The ICCCS 2004 Symposium had just finished that day and Dr Gail reported that there had been approximately 280 participants and the organizing committee was satisfied with the number and quality of the papers.

**ICCCS 2006**

The Chinese delegation reported that the preparations for the 2006 ICCCS Symposium to be held in Beijing, China were going well, with an international group of experts giving support. All presentations will be in English. The venue of the 2008 Symposium is uncertain but the 2010 symposium will be in Yokohama, Japan.

**Web Address**

Bill Whyte, who is the editor of the ICCCS web site, reported problems with the ownership of the web address 'ICCCS.org'. It has been taken over by a Swedish company that was not willing to hand over ownership to ICCCS. The Council decided to stop all actions to recover the web address 'ICCCS.org' and to change the web address to 'ICCCS.net'.

**New Chairman of ICCCS**

Prof. Wang Yao, Head of the Chinese delegation accepted the position of Chairman. The Chairmanship will start on 1 October 2004 and therefore coincides with the 2006 Symposium in Beijing. It was agreed that the next Council of Delegates Meeting shall take place in Moscow during September 2005. (It is likely the ISO Technical Committee 209 will meet at the same time and place.)

**ICCCS 2006**

**18th International  
Symposium on  
Contamination Control  
September 2006  
Beijing, China**

**Sponsors:**

ICCCS and Chinese Institute of Electronics (CIE)

**Organiser:**

Chinese Contamination Control Society

This will be the first time that the ICCCS symposium will be held in China.

Visits: Tour of the Great Wall, Underground Palace and Forbidden City. Registered representatives - free.



Tour to the unearthed soldier statuary in Xi'an City. Moderate cost.

With the fast development of cleanroom technology in China and its huge market potential, especially after the SARS epidemic, cleanroom technology has gained a great deal of attention in China.

In China, it is estimated that the market potential for cleanroom technology would be over 1.6 billion Euros each year. The markets are mainly located in eastern and southern China with over 500,000 people working in this field.

**Contact:**

www.cccs.org.cn  
email: cccs@cccs.org.cn

## CHAIRMAN'S REPORT

### Membership:

Total number of members is 1000 .

### Meetings and Courses:

In the year 2003-2004 S2C2 ran 2 courses and held 2 meetings.

#### Courses:

[1] Cleanroom Technology and [2] Cleanroom Testing in which some of the group sat their Cleanroom Testing and Certification Board examinations.

#### Meetings:

[1] Cleanroom Design including a site visit and [2] ISO 14698 Parts 1 and 2.

### Cleanroom Testing and Certification Board Summary:

This course has now been running 2 years and was designed to address current concerns regarding the standard of testing being carried out in cleanrooms. [See Issue 44 of *The Cleanroom Monitor* for background information.]

Four cohorts of students have completed the course based in Scotland. (The course has also been started in Ireland and Sweden.)

#### Statistics - in Scotland only:

Total number of students attending to date = 76

The students are divided into Professional (cleanroom testing engineers) and Associate (candidates who have an interest in cleanroom testing).

Total number of "Professional" students registered = 50

Total number of students presented for exam = 37

Total number of students who passed = 25

Therefore:

pass rate = 67% or, more worryingly, a failure rate = 33%.

### Cleanroom Technology Course:

All 5 people presented for the exam passed as listed below.

Report by *Lynn Morrison, Chairman*

## CLEANROOM COURSE PASSES

All 5 who sat the exam in October 2004 passed. They are:

*Mr S Pachnis*

Sendo Limited, Hatchford Brook, Hatchford Way, Sheldon,  
Birmingham, B26 3RZ

*Ms E McCracken, Ms S Crowhurst,  
Mr D Robson, Mr R Dorris*

Serologicals Ltd, Fleming Road, Kirkton Campus,  
Livingston, West Lothian, EH54 7BN

## THE WEBSITE

### Survey of one week:

In the week of October 3-9, 2004 the following picture emerged:

Total hits for S2C2 website = 24,314

This website [www.s2c2.co.uk](http://www.s2c2.co.uk) is the Scottish Society for Contamination Control based in Scotland, United Kingdom.

Once on the S2C2 home page there are 12 topics on offer for further viewing.

By far the majority of hits are the ICCCS Forum = 12,674

This website [www.s2c2.org](http://www.s2c2.org) is the International Confederation of Contamination Control Society's Cleanroom Forum and is run by S2C2.

### Who are they and where did they originate?

In this particular week most came in from Google and most spent from 1-59 seconds. 70% were from North America (i.e. USA, with a very small amount from Canada); 11% from Europe: mainly UK, then Germany, France and Belgium; 6% were from Asia and of that most were from India with Singapore closely behind.

While the main interest is definitely the Forum, it is worth noting that the next most visited section was Products and Services.

### Summary:

The activity on the Forum is viewed regularly by the web managers and therefore it is possible to see patterns emerge. Occasionally anomalies appear, e.g. one week in 2004 it was not the USA heading the league of Forum viewers and users but rather.....Equador.



## FORUM TOPICS

There is a broad variety of cleanroom related topics posted on the Forum. On the whole the pattern tends to be that 50 to roughly 200-300 people view one particular posted topic which interests them. However occasionally a topic exhibits a response that is outside the normal pattern, for example:

[1] #229 Auditing Garment Laundry (1175 views)

[2] #319 Goggle Disinfection (655 views)

[3] #169 Sporicides (476 views)

[4] #564 Overdesigned Clean Rooms (399 views)

[5] #427 Fed Std 209C or D (346 views)

and lastly [6] #888 [Am I in the Right Place?](#) deals with improving air quality, not in industry, but in the home.

## Part 3b: HOSPITALS - Laminar Flow ORs

### Cumulative Summary of Laminar Flow Ventilation:

This issue, [Issue 51] forms the fifth in a series of topics related to the history of laminar flow ventilation.

**Issue 47** highlighted the work of Willis Whitfield, the inventor of laminar flow cleanrooms. "A very basic objective was decided upon which, if could be met, would change the role of the clean room from a passive element to an active element in the contamination control chain."

**Issue 48** looked at laminar flow in industry. "Scientists at the Sandia Corp. in Albuquerque [where Whitfield was based and] where nuclear weapons are designed and assembled, have a passion for cleanliness."

**Issue 49** looked at laminar flow in hospitals. The new invention and development of laminar airflow devices for the military in the early 1960's very quickly caught the attention of the medical establishment. Dr J G Whitcomb in Bataan Hospital, Albuquerque wanted to explore the idea of installing a cleanroom in his hospital thereby developing the first laminar flow operating facility in the world.

**Issue 50** looked at the work of Sir John Charnley, an orthopaedic surgeon in the Wrightington Hospital, England, who, at that time (early 1960's) was working on exactly the same problem, namely, infection in operating theatres.<sup>1</sup> While Charnley is perhaps best known for his work on the design of hip joints he was also studying (and publishing) various ways of keeping bacteria away from the wound while operating and quickly saw how the concept of laminar flow ventilation might be applied. His original 'greenhouse' enclosure was adapted to take the new air handling and diffusion system and in 1966 Charnley and Howorth went on to produce the first permanent downflow enclosure.

### Two Types of Ventilation in Operating Rooms:

#### [1] Conventionally Ventilated

Before and during the 1970's a well-designed operating room was ventilated by a positive supply of filtered air from either diffusers in the ceiling or from a high-level wall grille. The supplied air was mixed with room air in a turbulent way and diluted the bacteria. The recommendations given in the Joint Working Party Report suggested approximately 20 air changes per hour for a standard size of operating room. The method of ventilation of these rooms is described as 'conventionally ventilated' or by the more recent description of 'non-unidirectional'.

Operating rooms designed to the Joint Working Party Report gave airborne bacterial counts of between 50 and 400 bacteria-carrying particles/m<sup>3</sup> depending on the number of people in the room and their activity during the operation. In surgical operations with a minimum of people in the room and the surgeon carrying out an operation with no strenuous movements, counts were normally below 100/m<sup>3</sup>. However, in an operating room where there was much activity and

many people e.g. a hip implant operation carried out in a teaching hospital, counts could reach 400/m<sup>3</sup>. This was a considerable improvement over the several 1000's of bacteria/m<sup>3</sup> found in unventilated or extract-ventilated rooms. However, it was felt that improvements were still required.

#### [2] Unidirectional Flow

In their 1960 research paper Blowers and Crew<sup>2</sup> reported an attempt to obtain a downward 'piston' of air (unidirectional flow, although they did not call it that) from an air diffuser (a hessian sheet) fitted over the complete operating room ceiling. They used the same amount of air supply as used in a conventionally ventilated operating room, and the downward velocity was thus only a few feet per minute. Unfortunately, because of this low air velocity, the thermal air currents from people and operating room lamp, and the movement of people, the airflow was disrupted and it was not possible to achieve good unidirectional airflow.

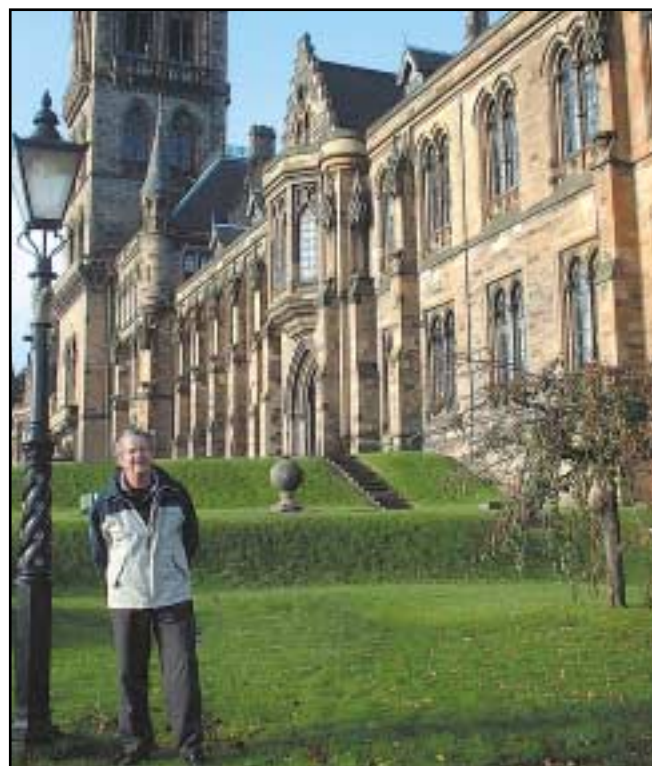
#### Bill Whyte, Microbiologist:

Bill, who is the founder and driving force of the Scottish Society for Contamination Control recalls: "In 1972, a Joint Working Party of the DHSS and MRC, of which I was a member, produced a document<sup>3</sup> updating the Medical Research Council report of 1962. The recommendations were used as a design brief for research relating to ventilation in operating rooms".

This was in the early days when he was based at Glasgow University doing research relating to airborne infection in surgical wards as well as the design of conventionally ventilated hospital rooms.

This study proved to be the starting point for his life's work and many publications in the field of contamination control.

Many are contained in his DSc Thesis of 2002.<sup>4</sup>



## Part 3b: HOSPITALS - Laminar Flow ORs

He says in his thesis: “Using the knowledge that existed at the time (1961), Howorth and Charnley attempted to perfect the ‘piston effect’ of a downward flow of air. Instead of using the whole of the operating room ceiling (as Blowers and Crew had done) they restricted the air supply to a small area and hence increased the downward velocity of the air. They used a 7ft x 7ft-area ‘greenhouse’ placed within the operating room.

The initial design did not produce good unidirectional airflow, but it was a clear step in the correct direction. The air supply volume was increased and design improvements incorporated that gave a reduction in airborne bacteria. The knowledge gained from the work on laminar flow (unidirectional) flow systems in the USA and my own research in the UK was later incorporated by Howorth Air Conditioning and good unidirectional flow achieved.”

In these early days of laminar flow, it was not possible to purchase a system for such a study to be undertaken so Bill designed and built one at Glasgow University, Department of Mechanical Engineering and installed it at Killearn Hospital.



### Orthopaedic Hospital, Killearn, Glasgow

The photograph below is first laminar-flow ventilation system in the UK built for an operating room. Professor Barnes, head of the Department of Orthopaedics at Glasgow University, made available the operating room where the new system was installed. This was in the orthopaedic theatre at Killearn Hospital, Glasgow in 1970.

As a matter of historical interest, the ‘hospital’ was, in fact, a collection of EMS wards, i.e. Emergency Medical Service huts placed out in the countryside during the period of the Second World War in readiness for an increased number of neurosurgery and orthopaedic patients.

The department with its patients later moved to Gartnavel General Hospital [a new hospital where the elective orthopaedic unit was re-sited] within the city of Glasgow and the laminar flow unit in the operating room continued to be used for another 29 years.

### David Hamblen, Orthopaedic Surgeon

In charge of the department and giving helpful and co-operative assistance in this research was Professor David L. Hamblen.

David arrived at Killearn Hospital in 1972 where the laminar flow operating theatre was already installed and had been there for two years. David and Bill worked together with Bill doing the microbiological work and David, the surgeon, in charge of the operating theatre and fully participating in the study, e.g. supplying the wound wash-outs for testing.



*Photo: Orthopaedics Today International*

David recalls “What Bill did was to install a ventilation system which had the ability to deliver air vertically (which is now the accepted norm) or horizontally. It was the same filtered air but you could put it in from either the top or from the side. This meant that we were in a position which Charnley wasn’t (because he had it coming from the ceiling downward) i.e. to actually compare the issue of the infection rates, or anything else, between horizontal and vertical laminar flow.

Why would you look at that? If you are not building from scratch it is much easier to install a horizontal flow into an existing operating theatre. Otherwise you have to build it as almost new.

They have got better areas where you put the motors and all the other things otherwise it is very low. In fact, Charnley’s original ‘greenhouse’ was quite a low roofed affair because of that. Certainly, in these early days they were pretty large and

cumbersome.

What emerged from the study was that you do get more air contamination from horizontal than vertical flow because skin particles shed by the staff are blown into the wound if the air flows horizontally rather than vertically. However, that doesn’t apply to all operations. For example, if you are doing a knee operation where you are end-on to the patient probably the horizontal flow is more efficient than vertical flow, but, nowadays, vertical flow is the norm for new installations.

The other thing that was built into that installation was the connections to allow people to work in ventilated ‘space’ suits. One of the problems with laminar flow is that, by and large, people don’t like working in those suits. The nurses object because it is hassle for them; a lot of people don’t like them because they get too hot, even if they are cooled, and there are communication problems, e.g. microphones. So

## Part 3b: HOSPITALS - Laminar Flow ORs



**The remains of Killearn hospital today**

when people used the new laminar flow they tended not to like working in this way and so very quickly they abandoned it especially if they were not part of a particular research project - surgeons being surgeons and nurses being nurses.

This is really what led us, then, to look at the clothing issue. The old operating gowns were made of balloon cloth which really was like operating wearing something with holes in it as far as skin shedding was concerned. When you shed skin particles you shed bacteria on them. Bill did a lot of work with various clothing companies where he looked at the design of hoods and gowns with cuffs both at the wrists and the ankle. He also looked at comfort against how much bacterial particles they shed. We did a lot of that work in a special shed chamber, like a shower cabinet and exercise where counts could be made of the particles shed.

Different sampling methods for bacterial contamination were also looked at. What is the best method? Air counts or settle plates or wound wash-outs using saline? The results of the tests had to be interpreted bearing in mind which sampling method was used.

Charnley managed to get his infection rate down to under 1% but other people struggled to achieve this figure (for various reasons, e.g. clothing used). The other thing that was difficult was that Charnley did all his procedures by using a series of instrument trays which were passed into the enclosure. For example, there was a tray for the initial stage of opening the wound, then there was another tray for each stage which were passed through in turn. This was very labour intensive for nursing staff and it also meant that you had to have a lot of instruments for sterilization. That was not so well accepted by the traditionalists who like to lay the instruments out in another room, although they could become contaminated. They were covered but they could still become contaminated. So in an ideal world you would have a series of trays coming into an enclosure but that was very rarely applied. So it is possible to see that there were a number of reasons that it was hard to reproduce Charnley's results entirely.

The infection rates did come down and everyone talked about

1% though it was probably something like 1 to 2% but that is still OK. What was really the problem was that some patients, after being alright for a year or eighteen months, would develop late infections which were hard to diagnose because the bacteria would not grow. This was because we discovered that they were what we call 'feeble pathogens', that is, these bacteria do not normally cause disease but they can, in the right environment give you problems. An example of this is having a joint replacement because it is foreign material and this material can be colonized by these bacteria and then lie dormant for awhile. Then they emerge, for example, if the patient's resistance is lowered because of some other condition. That brought about a new concept, not just in how

you control it but also how you treat it because many of the bacteria were resistant to the antibiotics used for prophylaxis.

Also in the 1970's more powerful antibiotics became available and that again persuaded a lot of people that they did not need laminar flow, or if they did, they could cut corners a bit. We paid a penalty on that because more and more bacteria have become resistant to the antibiotics.

In the early days Charnley did not use antibiotics. It was one of the problems in the multi-centre trials that he didn't like: normalizing all the factors, i.e. how people could be allowed to use antibiotics as well as his system. However, eventually, he began to realize that you had to use antibiotics as well.

The real problem that never got fully resolved in that area was that a lot of people used antibiotics in the bone cement at the primary operation, particularly the Scandinavians. We never used it except for second time surgery. Their results, particularly in the multi-centre trials, were clouded by the fact that they were putting antibiotics in all their cement.

That was one reason why you had to have multi-centre trials because there were so many variables that differed between centres.

For every technical advance there is a counter-current of pressures: cutting corners, sloppy theatre discipline. For example, he [Charnley] used to have control of their own instrument sterilization, but then it was moved outwith the hospital. If instruments were dropped you didn't have instant access to a sterilizer and you had to open another tray. Another problem was that general surgeons decided that theatre masks were a waste of time and you did not need them. They got a bacteriologist to show that even if you did not wear a mask the infection rates did not go up. This applied, of course, to the general surgical operations where infection rates were higher anyway and you were not going into high risk areas like bones and joints. That just reassured the anaesthetists who never liked wearing masks anyway and liked wandering in and out of theatres. So theatre discipline became steadily less rigid.

## Part 3b: HOSPITALS - Laminar Flow ORs

*Once you install laminar flow ventilation people think they can just wander in and out at will, half dressed, undressed; it becomes sloppy.*

We have never been able to persuade people to re-introduce tighter theatre discipline. If you could add that to the new technology, then you have a chance of really bringing the infection rate close to zero. But that is human nature; it will always catch you out.

There is always more and more bureaucracy, for example, setting standards, but the actual implementation of these on the ground gets less and less tight.

Certainly, the design of the laminar flow installation has changed. It went from the original, rather cramped 'greenhouse' to a better thing. The one we had at Gartnavel was a structure that went virtually to the floor, i.e. not quite to the floor as you have to have air coming out the bottom. Later designs were based on the fact that people said that if you have enough velocity in the vertical flow, you actually don't need it down to the floor. You just have the structure at the top to direct the flow. I am not entirely convinced that that is strictly correct."

### David visited Charnley

"I went to Edinburgh in 1967 and about 1968 or 1969 I went down to visit him. If you wanted to use his system of instruments, you had to go and do a two or three day visit to Wrightington to see how he did it. You had to see his system, how the instruments were used and understand the principles. When you had done that you were then allowed to buy the instruments from the manufacturers, otherwise they wouldn't release them.

Another interesting point that has never been reproduced, not entirely relevant to the infection problem, is that, since then, manufactures will just give their instruments to anyone, whether they are trained or not. Of course, orthopaedic surgeons (who are really toys-for-the-boys people) love having new toys and so, sometimes, people who shouldn't get their hands on new stuff, do. So in a sense Charnley was a pioneer because he wouldn't release anything unless you had been down and he thought you were OK. But no one has ever been able to implement that since."

The years spent at Killearn by Bill and David were not without frustrations.

Bill recalls: "The operating theatres in these huts used to get very warm. People would open the windows and they got upset when a bee or a fly came in! Muslin was then put over the windows and they installed the motors outside the room to help assist with cooling."

David recalls: "When the Killearn department moved to Gartnavel General Hospital they arranged to have the laminar flow unit moved across and re-installed in one of the new theatres there. After a few years the old one broke down; it had been causing over-heating problems for the theatres and various other things that they couldn't cope with so they replaced it with a new one which turned out to be less efficient but that is another story!"

## REFERENCES

- 1 Charnley, J. (1972). Post operative infection after total hip replacement with special reference to air contamination in the operating room. Internal Publication No. 38, Centre for Hip Surgery Wrightington Hospital, Wigan.
- 2 Blowers, R. & Crew, B (1960). Ventilation of Operating Theatres. *J. Hyg., Camb.* **58**, 427-448.
- 3 Report (1972). Ventilation in operating suites. Report of the Joint Working Party of the DHSS and MRC. Medical Research Council, London.
- 4 Whyte, W, DSc Thesis, Control of Airborne Microorganisms in Surgical and Pharmaceutical Cleanrooms, University of Strathclyde, Glasgow, November 2002.

## BIOGRAPHY

Professor David Hamblen graduated from the London Hospital in 1957; after further training in London, Birmingham, and Harvard University in Boston, Massachusetts; was appointed Senior Lecturer in Edinburgh, and then Professor of Orthopaedic Surgery in Glasgow / Honorary Consultant Orthopaedic Surgeon to the Greater Glasgow Health Board from 1972 to 1999.

He held several offices with the British Orthopaedic Association including Chairman of its Education Committee, Chairman of the Research and Scholarship Committee, and then served as President in 1990/91. He was made an Honorary Fellow of the Association in 2001.

He has served on a number of National Committees and Boards including the Medical Research Council, Arthritis and Rheumatism Council, The British Council, Chief Scientist Committee of the Scottish Office, and Action Research Advisory Panel on Medical Engineering.

He is a past President of the British Hip Society and Chairman of the Association of the Professors of Orthopaedic Surgery. In 1992 he was made a member of the Council of Management of the British Journal of Bone and Joint Surgery and served as its Chairman from 1995 to 2002.

He served as Chairman of the Greater Glasgow Health Board from 1997 to 2002 and is joint author of two well-established undergraduate textbooks: Outline of Orthopaedics (13th edition 2001) and Outline of Fractures (11th edition 1999).

His major clinical interests were in joint replacement, including revision surgery, and musculo-skeletal tumour surgery. His laboratory research centred on the use of hyperbaric oxygenation for treatment of chronic bone infections (subject of his PhD) and on the biological mechanisms responsible for bone resorption around loose prosthetic implants.

In 2002 he was made a CBE and in 2003 was awarded Honorary Doctorates of Science from the Universities of Strathclyde and Glasgow.

## ISSUES AT BRUSSELS CTEC 2004

The Cleanroom Technology Exhibition & Conference held in Brussels on October 12-14, 2004 brought together key people in the industry. Many issues facing the industry today were examined of which the following are an example:

### [1] New standards.

One of the key issues is the new set of standards which are not well understood, let alone even fully available. This is creating a certain degree of uncertainty in the pharmaceutical industry. It will only be a matter of time before these standards become accepted as the norm. However, for the time being there now are a set of standards that are trying to do things that the old standards never did, in particular, giving the full range of answers. This is something that people are wanting to know more about and wanting to understand more. For example, what are the differences between ISO and Fed Std 209?

Ken Goldstein shed light on this in his presentation.

### [2] The problem of monitoring isolator performance when in use.

While it is standard practice to monitor and control a cleanroom in use, it is difficult to do this in an isolator due to the cramped space, and the particles generated during production activities. Furthermore, it can be an intrusive activity that risks compromising the isolator, thus negating the benefit of the isolator.

#### **Sterilization of Isolators**

It is now common practice to use vapour-phase hydrogen peroxide to disinfect and sterilise isolators. However, during cycle development and validation, some random positive Biological Indicators (BI's) can be expected to occur. It is difficult to show (after a cycle) if these positive BI's indicate inadequate process lethality or are the result of variability in the BI batch ie are "rogue" BI's. Tony Byrne will present a talk in the University of Warwick on December 6th on the sterilisation of isolators using vapour-phase hydrogen peroxide and a method of showing process lethality even if random positive BI's occur.

### [3] The 5 micron number problem.

This is in relation to the Annex 1 and requested revisions from the industry in relation to 2 parts: (i) the statistical significance and the sample size and (ii) the difficulty of measuring zero, and now one particle, at 5 microns.

The statistical number in the ISO 14644-1 of 5 micron particles/m<sup>3</sup> as the class limit is 29 so in the way the zones are interpreted, particularly in Grade B (and at Grade B it has to be taken back to a change area) you are now looking at a maximum reading of 1 particle at 5 micron and greater size, all the way from the Grade B change room to the Grade A zone.

It is highly unlikely that you would not see at least one particle at this 5 micron and greater size which may in fact be a spurious reading due to a counting error or any number of other reasons BUT impose a FAIL verdict.

The FDA has wisely ignored the 5 micron and greater size level and relies on microbiological and other measurements to establish compliance.

The view of many in the cleanroom industry is that a count at 5 microns should not, on its own, be a pass-fail criterion. It should be used as part of a number of other measurements that will dictate the performance.

### [4] One metre cubed sample volume.

The change from cubic foot to cubic metre and the requirement to take a sample volume of one metre cubed which is 35-odd cubic feet. The question now is whether that one metre cubed sample volume relates to a zone or does it relate to a measuring point? It is open for interpretation. Basically, a huge amount of additional testing time is involved if it is 1 metre cubed per sample point vs zone.

David Hall of Particle Measuring Systems brought out this point in his presentation as did Brian Fox who is doing a regulatory comparison of EU Annex 1 vs FDA's new guidelines.

#### CONTRIBUTORS TO THIS ARTICLE:

Conor Murray, Chairman, Irish Cleanroom Society, Director, Ardmac Cleanrooms, Coes Road, Dundalk, Ireland. (conor.murray@ardmac.com)

Tony Byrne, Senior Director Development, Organon (Ireland) Ltd, P.O. Box 2857, Drynam Road, Swords, Co. Dublin, Ireland.

Jim Stracey, Pharmaceutical Specialist, Design and Management, AMEC Group Ltd, Timothy's Bridge Road, Stratford-on-Avon, Warwickshire, CV37 9NJ.

## PROBLEMS WITH ISO 14644-1 and 2?

In 1999, the new ISO standard 14644: Part 1: 'Classification of air cleanliness' was published. This gives the airborne particle limits for cleanrooms. In 2000, ISO 14644: Part 2: 'Specifications for testing and monitoring to prove continued compliance with ISO 14644-1' was published. ISO standards published over 5 years can be revised. At a recent meeting (September 2004) of the main ISO committee dealing with the cleanroom standards (TC 209) it was resolved that Working Group 1, who is responsible for both of these standards, would be reconvened to prepare a list of possible changes for ISO 14644-1 and ISO 14644-2.

S2C2 will produce a list of suggested changes and submit it to British Standards Institute for consideration as part of the UK submission to WG2. These comments will be published on the S2C2 website in the 'Current Topics' section.

## 3C at NEC, BIRMINGHAM, FEBRUARY 16-17, 2005

### Two Educational Cleanroom Courses

organised by the S2C2 and presented by industry expert Bill Whyte

Wednesday 16 February - CLEANROOM TESTING COURSE for people wishing to understand how a cleanroom must be tested to comply with cleanroom standards.

Thursday 17 February - CLEANROOM TECHNOLOGY COURSE is a basic course covering all aspects of cleanroom technology and is for those relatively new to the subject, or who wish to brush up their knowledge.

People attending the courses can attend the 3C Exhibition



Contact Liz Bokaie on 02028 991 1067  
email [liz.bokaie@octomedia.org](mailto:liz.bokaie@octomedia.org)  
visit [www.threec.co.uk](http://www.threec.co.uk)

Price per half-day course is £100 (£117.50 inc. VAT)



Contact: Kay Johnston on 0141 330 3699  
email: [s2c2@mech.gla.ac.uk](mailto:s2c2@mech.gla.ac.uk)  
[www.s2c2.co.uk/events/c20050216.html](http://www.s2c2.co.uk/events/c20050216.html)

## PIUG, WARWICK, DECEMBER 6-8, 2004

### 8th Pharmaceutical Isolator User Group Conference

6 - 8 December 2004

University of Warwick Conference Centre, Gibbet Hill Road, Warwick, UK

The conference is designed for both those involved and those who are likely to become involved with Pharmaceutical Isolators. It will consist of a blend of plenary and interactive seminar sessions as well as an associated exhibition.

#### *Participants:*

**Brian Midcalf, Jack Lysford, Tony Byrne,  
Brian Bergin, Ron Feakes, Graham Steele,  
Jon Nottingham, Bushrah Sajit, Alan Mills,  
Gordon Farquharson, Graham Hill, Volker Sigwarth,  
Lynn Carroll, Tim Coles, Bev Ellis, Lynn Morrison,  
John Neiger, Bob Pringle, Karen Rossington,  
Sarah Ryan, Richard Bateman, Peter White**

**Contact: Professional Lifelong Learning Unit  
School of Continuing Education,  
University of Leeds, Springfield Mount,  
Leeds, UK, LS2 9NG**



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email [s.c.harker@leeds.ac.uk](mailto:s.c.harker@leeds.ac.uk)    Also [www.piug.org.uk/conf.html](http://www.piug.org.uk/conf.html)**

## CLEANROOM GARMENTS - NIGEL SLATER



### Introduction:

Nigel Slater has been in the garment industry and in the business of manufacturing cleanroom garments for the past 16 years.

### New Business:

“About 2 years ago I decided that I could perhaps do with a change. You reach a point where you want to spread out and try something else.

Over the 16 years I have learned a lot about cleanrooms - not only cleanroom garments but also different aspects including laundry, cleaning cleanrooms, static and consumables. I thought that a move into a consultant’s role would enable me to share this with other people in the industry.

I have given talks and presented papers to S2C2 in the past, also Cleanrooms East in USA, Cleanrooms Europa in Holland, Pharmaceutical Cleanrooms in the UK, Nordic R3 in Scandinavia and written articles for various journals.

I have seen the sophistication of cleanrooms change greatly. When I first came into the industry there was only one cleanroom fabric which everyone used. That was ceramic Terylene (or ceramic polyester) which was originally designed for the ceramics industry in Stoke to stop the ingress of particles on to people.

Cleanroom fabric works the other way around. It stops particles moving from people which might contaminate the atmosphere. Since then there has been a development and sophistication of cleanroom fabrics to the state where we are today.

I am based in Manchester, in the north of England, but I cover Europe and the Far East with consultancy. I have customers in many countries where I am able to give advice. I used to be with Contamination Control Apparel (CCA Ltd) but now I have my own company and it is called CM Supply.

There are 2 or 3 people with whom I have a loose association so that we can complement each other on various aspects of consultancy topics. It helps to provide joint solutions to problems either of us might come across in the the contamination control industry.”

CM Supply covers 5 areas:

- [1] Cleanroom garments and fabrics
- [2] Cleaning a cleanroom, equipment usage
- [3] Laundries, laundry contracts, and laundry auditing
- [4] Consumables, auditing to see if they are right and fit for purpose
- [5] Education and training such as static, cleanroom behaviour and operating procedures, e.g. donning garments.

Nigel’s background is in textiles, weaving, bleaching and dyeing. He joined a bleaching and dyeing company when he was 20 years old and gained experience in the basics before moving on to a company who manufactured fabrics. The move into Contaminated Control Apparel who manufactured cleanroom garments meant he went with a lot of basic knowledge of weaving and the construction of fabrics. Therefore as cleanroom fabrics have progressed he has been able to move along with them and appreciate the mechanics of the manufacturing. This meant he could help people who were trying to achieve different things, for example, using microfibres.

When not working he likes scuba diving both in the UK and abroad. Also he is good at building kit cars. He built a Westfield 7 which is a 2 seater performance car which he still owns and uses but he keeps a Ford as a workhorse.

Nigel enjoys his work in what he describes as “a very niche area”. Business is good. He likes to be able to help all the new-comers to the industry and enjoys working with numerous friends and contacts he has made over all the years that he has been in this industry.

Contact:

CM Supply

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Interested in garments? Refer to the FORUM on page 3 which notes a 5 fold level of interest in “Auditing Garment Laundry”.

# THE INDUSTRY

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### 2. New office:

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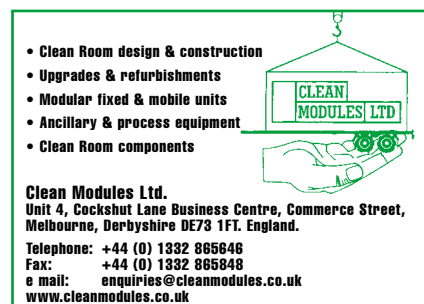
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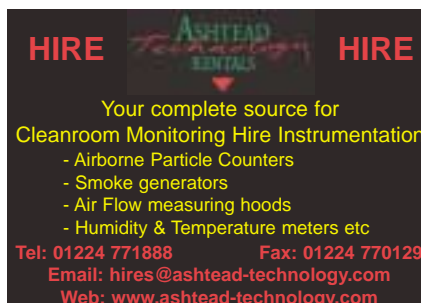


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