THE CLEANROOM MONITOR

S2C2

The Scottish Society for Contamination Control

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- ISO 14698 & RISK MANAGEMENT
- EN 1822
- LAMINAR FLOW
- HOSPITALS
- NEWS
- YELLOW GUIDE
- CLEANROOM TESTING COURSE

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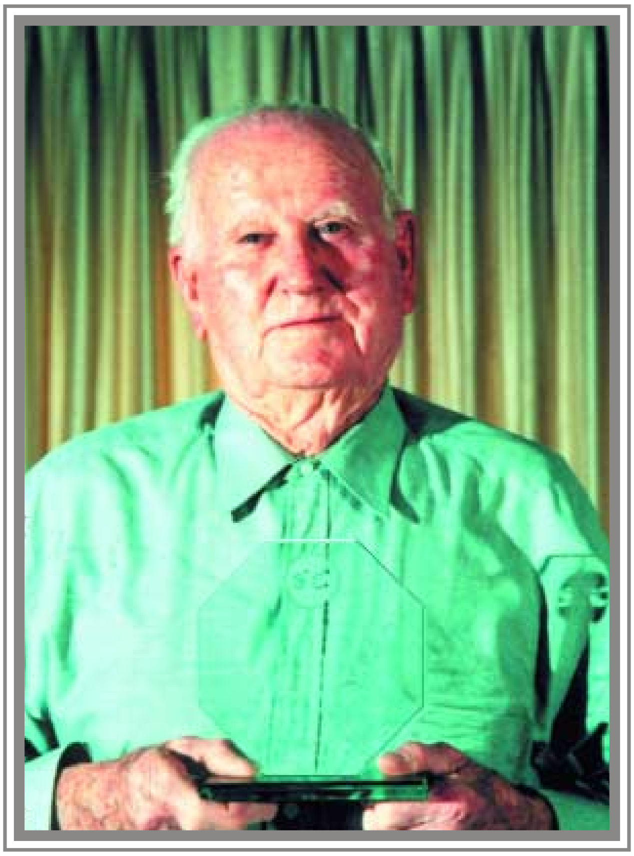


HONORARY LIFE MEMBERSHIP FOR WILLIS WHITFIELD

Willis Whitfield, who lives in Albuquerque, New Mexico, USA, holds his award which has been given to him by the Society. His work, and that of his colleagues, is the origin of what is now regarded as "the cleanroom industry". He is the man who invented laminar flow cleanrooms and the laminar flow air hood. Issues 47, 48 and 49 of *The Cleanroom Monitor* highlight his work using archive material kindly supplied by him to the Society.

The writing on the crystal award reads :

Willis Whitfield - in recognition of outstanding pioneering discoveries in cleanroom technology.

ISO 14698 and RISK MANAGEMENT

After a wait of many years, ISO 14698-1 and ISO 14698-2 have now been published. These standards contain new requirements for cleanrooms where micro-organisms have to be controlled.

Forty people attended a meeting run by S2C2 in Glasgow on March 25, 2004 where Bill Whyte and Andrew Tweedie talked about the new standard. Bill was involved in the writing of the standard and while it is not perfect, he feels that the parts that consider risk management of microbial contamination and validating air samplers are a significant contribution to contamination control. Both he and Neil Stephenson spent a lot of time trying to make it readable.

The crux of the document is that you are required to establish a risk management system and much of the document gives methods of how to monitor it. In the area of contamination control we are talking about the risk of microbial contamination.

If risk can be said to be "the combination of the likelihood of an event occurring and the severity of its consequence", then, translated to the area of biocontamination, the following equation is:

Risk of microbial contamination = severity *x* occurrence

The next step is to quantify this concept scientifically. The standard offers a means to do this by the establishment of a "formal system", i.e a Risk Management System.

Bill talked about putting risk management into the system and Andrew talked about measuring it.

[1] The Risk Assessment Model:

How often do people go into a cleanroom and assess the risk of microbial contamination by use of a model that is anything approaching scientific?

In this standard, the first line of the normative part, i.e. that which is compulsory, states: 'A formal system of biocontamination control (Formal System) shall be established, implemented and maintained within cleanrooms and associated environments. The formal system will assess and control factors that can affect the microbial quality of the process and product."

There are different systems of Risk Management

HACCP - Hazard Analysis and Critical Control Point

This was invented by and developed for the food industry. It is a method of looking where hazards may be, assessing the risks and then managing them.

And in electrical and mechanical manufacturing:

FMEA - Failure Mode and Effect Analysis

FTA - Fault Tree Analysis

HAZOP - Hazard Operational Studies

The FMEA system can be used in assessing microbial contamination risk. A general method that might be used is as follows:

(a) Identify the sources of risk:

Firstly, you should think about what and where are the sources of contamination? In a cleanroom every source should be considered, at least in the beginning, as a potential hazard. Keeping in mind the sources, an example of 4 factors relating to contamination which might be considered for assessment are:

(1) *amount of contamination*
(2) *ease of dispersion*
(3) *proximity to critical area*
(3) *effectiveness of control method*

This is the first half of the model: it identifies the factors but not the risk.

(b) The risk, by definition, is the severity and the occurrence of contamination:

How bad is it? How often does it occur? Against each factor a range is described using ordinary words. Therefore:

(1) *amount of contamination*: Ranges from nil to high
(2) *ease of dispersion*: Ranges from nil to high
(3) *proximity to critical area*: Ranges from far to near
(4) *effectiveness of control method*: Ranges from full to none

A numerical value is then given to each description in the "range". Therefore, using (1) and (2) above:

nil = 0
very low = 0.5
low = 1
medium = 1.5
high = 2

Each factor is done in the same way. The factors are then multiplied together and the answer is called "The Risk Rating". And by the same process a High-Medium-Low Rating can be assigned. (This Risk Scoring System is usually assigned by an aggregation of opinion from an expert committee set up to carry out this task.)

So now you have a model - part art and part science - which is systematic in approach.

[2] Points raised from the discussion:

* Regulatory people are looking for Risk Assessment exercises.
* The standard is a collection of opinions and therefore is only as good as the sum of those opinions.
* This standard does not say what you have got to do. It just gives methods of monitoring and looks at risks and measuring. You have just got to do what you feel in your own situation is common sense.
* To implement it, it says what you must consider, but the problem is how?
* Risk assessment gives you an idea of your problem, i.e. of how well you are doing.

EN 1822

Neil Stephenson is the official representative of S2C2 on the MCE/21/3 committee which is the British Standards Institute group that discusses and monitors EN1822, the European standard on the testing of high efficiency filters by the filter manufacturer. The Secretary of this committee is Audrey Erlem.

Neil feels it is important for cleanroom people to familiarize themselves with this standard as there are some conflicts that need to be addressed. Based on his many years of working in the field he talks about the issues, the problems and possible solutions.

Background:

The first parts of the standard were written 5 years ago and every 5 years it has to be re-examined. This review is currently on-going.

There have been considerable industry problems with it and the biggest problem is that, in Europe, the manufacturer's test method doesn't in any way match the DOP test method used as the in-situ test by the end user. Therefore you can buy a filter manufactured to EN1822 and it could fail hopelessly when you come to do an in-situ test.

The Americans do not have this problem as their manufacturer's test method matches the DOP photometry in-situ test beautifully. It really does work. I have done training sessions where I have had customers bring American filters out and we would test the American filter using the aerosol photometer DOP test and we would get exactly the same answer as is printed on their test certificate issued by the manufacturer.

What is Needed:

There are currently three possible final element test methods in EN1822. They range from a simple visual inspection using the paraffin thread method for H14 filters and below to the DPC (Discrete Particle Counter) scan method. None of the methods correlate to the DOP scan method commonly used for in-situ testing.

There should be a DOP scan method placed in the EN1822 standard thus allowing customer choice of the preferred test method.

How did we get into this mess?

EN1822 was constructed from a German DIN standard. One of the initial problems was that there was nobody on the committee who was out of the pharmaceutical industry. There were only filter manufacturers and nuclear people and that was it. The pharmaceutical industry cannot use the type of filter specified in the standard. Oddly the type of filter specified in the standard is not a reality in practice either! Sadly, the UK had the chairmanship of the group and we were still able to produce a standard which does not satisfy the majority of the pharmaceutical requirements.

Improve the Standard:

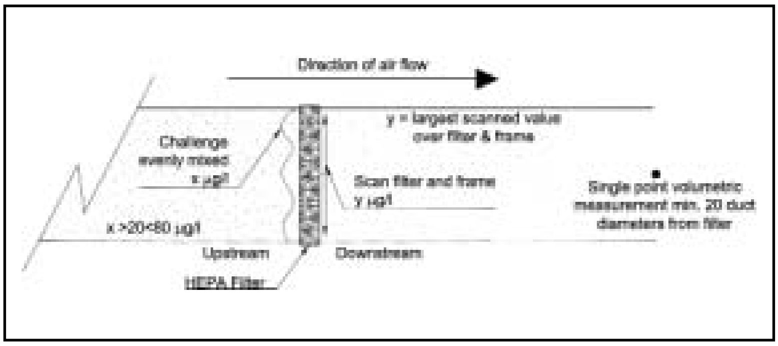
Our prime objective when we sit on these committees is to try and find solutions for people in the industry. Therefore if you produce a document that only applies to 10% of the industry it is not very helpful especially if it particularly excludes the pharmaceutical industry. It wasn't intended to but they didn't understand what a big impact it would have on the pharmaceutical industry. To be frank, it really didn't interest them. These issues were highlighted prior to publication and the answer was "if the H14 filter as specified in the standard does not meet your requirements then buy a higher grade filter." No consideration was taken into account of the extra energy costs which would be incurred because of the increased back pressures of the higher grade filters.

Here is the irony: This EN 1822 test method was introduced 5 years ago, A number of manufacturers in the UK developed test rigs (you could not buy them; they had to be specially made) with typical prices of £250,000 to £400,000! They are very complicated computer controlled automated systems, involving robotics and using particle counters - very great stuff.

It takes a long time to scan a filter and doesn't give a result which is any better than the old British Standard sodium flame test. There isn't one manufacturer that I am aware of, in this country now, who uses them. They mothballed the test equipment and have all gone back to aerosol photometry DOP scan testing.

General Filter Test Methods - Overview:

Essentially there are 2 types of test method: one is a scanning test method where you scan the face of the filter and the other is volumetric test method which dilutes any leaks in the filter with the total air volume. You then make a single point measurement well downstream. The two methods report their results as a % penetration but they have completely different meanings. The single point volumetric measurement is, therefore, somewhere in the region of two to three thousand times less sensitive than the scan test. The result is also volume flow related. Double the volume through the filter and the reported volumetric size is halved!



continued on page 9

Part 3a: HOSPITALS - Sir John Charnley

In the past three issues (Issue 47, 48 and 49) the development of laminar flow in cleanrooms has been featured through the use of archive material provided by its inventor, Willis Whitfield (who still lives in New Mexico, USA).

In Issue 49 it was seen how, in 1962, Dr John G Whitcomb, a surgeon based in the same city as Willis Whitfield very quickly saw how this new technology might help to provide a solution to the problem of infection in his operating theatres.

At this time, John Charnley, based in the UK was already working on this problem as well. Charnley (1911-1982) was an orthopaedic surgeon who, from the 1950's onwards, did innovative work in relation to hip replacement surgery. He established a very high reputation at his Centre for Hip Surgery at Wrightington Hospital, near Manchester and trained generations of orthopaedic surgeons in his methods.

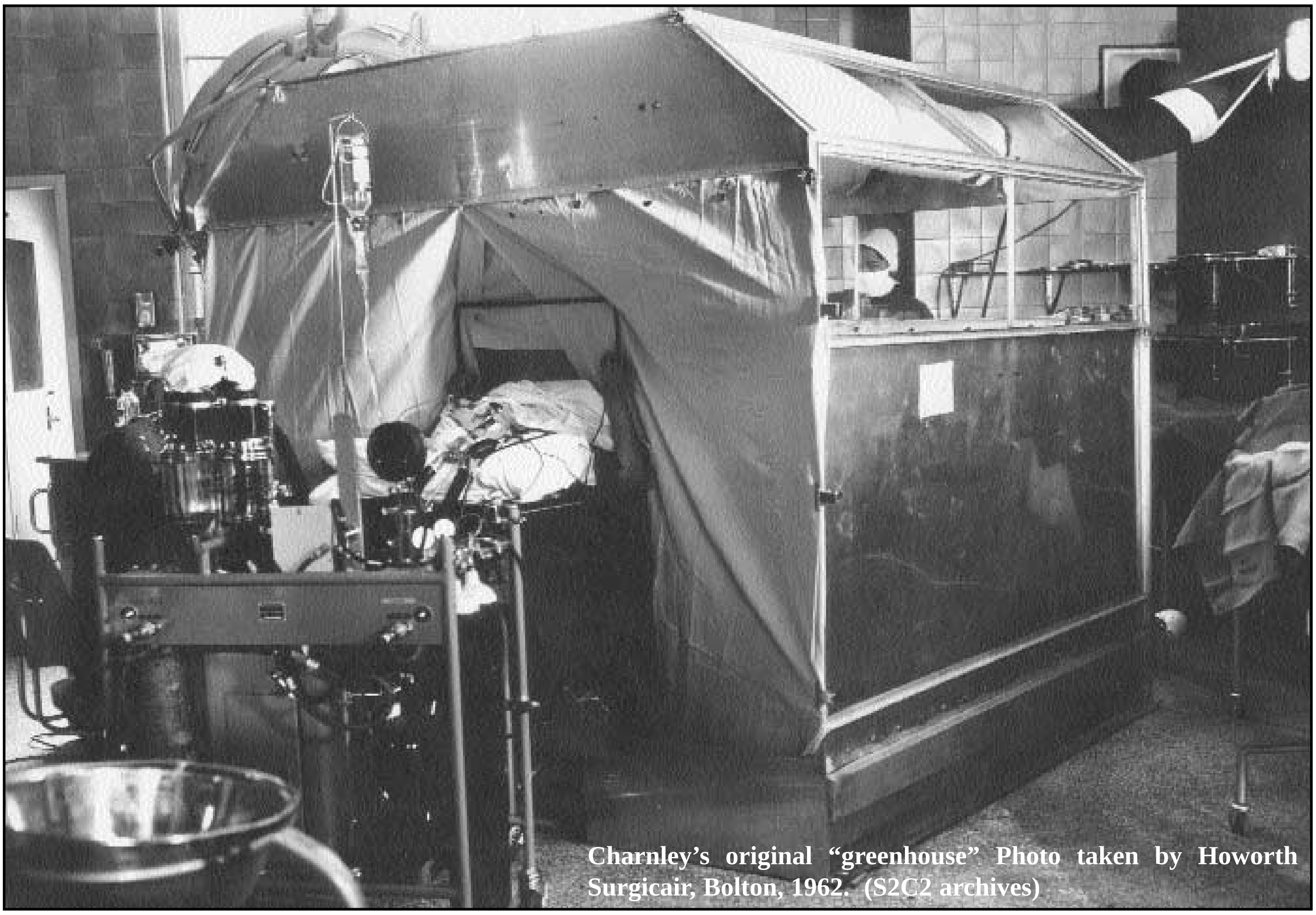
While he continued to work on the design of the hip joint he also spent a great deal of effort (and wrote many papers) his attempting to reduce contamination in the operating theatre by the use of clean air. This, and his development of special surgical clothing, is described in by W. Waugh's book."John Charnley - the man and the hip" [1]

Like Joseph Lister (using his carbolic spray in 1867) Charnley felt that air in the operating theatre probably played a role in post-operative infection. Both Lister and Charnley managed to reduce the infection rates post-operatively but as no scientific trials were undertaken at the time, the reasons for the improved results, in both cases, were always open to question. For example, while using carbolic spray Lister would be introducing other changes in his operations and similarly, Charnley, a century later, would be introducing, coincidently, new materials and working practices as he operated in ultra clean air theatres.

The Problem:

Charnley described the operating theatre in the early days: "Throughout 1960 to 1962 Teflon (polytetrafluorethylene or PTFE) arthroplasties were performed at Wrightington in the crudest of operating theatres...An extraction fan was merely to keep the operating personnel in reasonable comfort; it was not seen as having any bearing on wound infection." [2]

Waugh states that "The infection rate after the PTFE arthroplasties was 7%, which now seems a horrifying figure, but there was an odd feature: the infection might develop three to six months after operation, and often after healing had occurred perfectly in the first instance. The wounds had all the appearances of infection, but if pus was discharged it was frequently reported as sterile - that is, no infecting organisms were grown in the laboratory by the techniques available at the time." [3]



Charnley's original "greenhouse" Photo taken by Howorth Surgicair, Bolton, 1962. (S2C2 archives)

Part 3a: HOSPITALS - Sir John Charnley


Howorth Air Engineering Ltd (S2C2 archives)

Charnley thought that the problem might be related to the acrylic cement used so he formulated a hypothesis: "If I could successfully prevent all bacteria gaining access to the wound...then two possible results might ensue: either the infection-like complications would become significantly fewer; or they would continue at the same frequency. In the first case bacteria would be responsible; in the second case the chemical action of the cement would be responsible." [4]

How he tackled the Problem:

He need to devise a method of keeping bacteria away from the wound during the operation. This was in the early 1960's when the new concept of laminar flow ventilation, for military and industrial use, was starting to become known.

He travelled to the USA to look at how laminar flow ventilation was being used in Baatan Hospital, Albuquerque.

Most of Charnley's measurements of air contamination were made using settle plates.[5] Culture plates in the theatre under normal conditions (unmodified theatre) were colonized by bacteria with a colony count per hour (cph) of an average of 80 to 90. This indicated high contamination of air. He decided to design an enclosure that could be used in the main theatre into which filtered air could be passed.

He constructed a prototype at Wrightington in 1961. It was 7 feet square and 7 feet high and was known as "the greenhouse". The air was ducted in from outside the theatre building and blown in by a small fan with an electrostatic precipitator which removed dust particles on which bacteria are carried. Although the air flow was not more than 40 cubic feet per minute the colony count was reduced to an average of 25 an hour.

Helping in the exercise of designing an enclosure was Mr F N Howorth whose long established (1854) air filtration firm in Bolton, Lancashire was in the business of designing filters to remove soiling particles from the air in textile factories and bacteria from the fermenting rooms in breweries. The early Howorth's brewery (and some pharmaceutical) filters consisted of large bags made with two layers of cotton blanketing. They were 98% efficient against particles up to 2 microns.

Part 3a: HOSPITALS - Sir John Charnley
continued

The original "greenhouse" was adapted to take the new air handling and diffusion system which Howorth designed and donated to the hospital (June 1962; see photograph on page 4). This continued to be used until March 1966. The main improvements were to do with the flow of filtered air which was increased from 40 to 800 cubic feet per minute and the number of air changes increased from 10 to 130 per hour.

The fall in the settle plate count went from an average of 25 to 1.8 colonies per hour.

Charnley and Howorth went on to produce the first permanent (Mark I) downflow enclosure which was installed in a second operating theatre in Wrightington in June 1966. The air flow was increased from 2000 to 4000 cubic feet per minute. Contamination was extremely low. Even after taking other factors into consideration, the infection rate fell to 3.7% and then to 1.3% as the clean air system was improved.[6]

Body suits:

This remaining 1.3% concerned Charnley so he began to look at the clothing and gloves. He started wearing 2 pairs of surgical gloves from 1966 onwards.

While the downflow of air in the enclosure would remove the scales of skin and the bacteria from the bodies of personnel in the operating theatre he spent a great deal of time and effort looking at ways of protecting the wound from outside contamination. (This was also a consequence of the fact that he felt that prophylactic antibiotics would only make the matter worse.) Therefore he decided to look at the material and design of surgical clothing.

The use of suction under the all-enveloping hoods (instead of the conventional surgical cap) made it possible for the surgeons to wear ventile gowns which were otherwise very hot. But Charnley found that there was very little improvement over the cotton gowns with which ventile was being compared. He thought the explanation was that heat from the surgeon's body caused a rising flow of air encouraging particles to escape from the upper part of the gown. This idea brought a solution to the problem: 'Through altering the design of the operating gown by incorporating the helmet into the gown (like that of the Ku-Klux Klan) and by closing the back of the gown completely so that it has to be put over the head like a night shirt, the use of body-suction has now produced a great improvement of the bacterial count of the air inside the enclosure....'[7] The infection rate was lowered to 0.6% in 5405 low friction operations carried out at Wrightington from January 1970 to December 1974.

The body exhaust equipment was made and marketed by Howorth.

Charnley and Howorth continued to modify and improve the theatre enclosures.

Howorth felt that the highest velocity of air flow should be at the centre and get less towards the periphery of the sterile area. He immediately applied for a patent and a scale model was made and tested at Glasgow University by Bill Whyte and worked perfectly. (Prototype exhibited in 1976.)

Charnley received many awards in his life including the Lister Medal and a knighthood.

However, also during his life his work was much criticized mainly because no scientific trials were undertaken at the time.

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7 Charnley J. (1964) A clean air operating enclosure. *British Journal of Surgery* **51**:195-202.

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Has Cleanroom Technology Left Hospitals Behind?
by Colin Perllman

One of the early uses of cleanroom technology, i.e. use of laminar flow ventilation, was in hospital operating theatres.

Since those early days, this technology has moved on at a rapid pace. However, the level of “acceptable” cleanliness in the installation in the past is not perhaps acceptable nowadays.

One would assume that when hospitals are refurbished the clean areas would have been brought up to the relevant standard. Why is it then that hospitals have a problem with contamination control when cleanroom technology was primarily developed to provide that control?

You only have to look at the problem of MRSA, E-coli, cleaning and decontamination. It is interesting to read about some of the measures being introduced to combat these problems as if they are new technology when most of them have been around for years. They are only new technology in the hospital sector and that is why I ask, has cleanroom technology left hospitals behind?

The basic requirement in hospitals is that of microbial contamination control and there are four areas in a hospital that have differing control requirements; the aseptic pharmacy unit, the operating theatre, the isolation ward and the general ward. Other areas such as the neo-natal and special care baby units are simply a variation of one of the above.

I have visited many hospitals during the course of my work and while some hospitals are better than others, all seem to make the same mistakes over and over again.

EXAMPLES:

Aseptic pharmacy units:

The aseptic pharmacy units are without a doubt very good at microbial control, as one would expect. The staff are usually very well trained in cleanroom procedures and usually have a very good understanding of how their cleanrooms work. They are let down however by the facilities themselves. Most of these cleanrooms are built using old technology by people

continued on page 8

Howorth Air Engineering Ltd (S2C2 archives)

Has Cleanroom Technology Left Hospitals Behind?

continued

that do not fully understand the requirements of the facility itself and which are then maintained by a maintenance company that has probably never seen a cleanroom until the day they walked through the door. This increases the workload of the pharmacy staff to maintain the aseptic condition of the facility and, of course, that in turn increases the running costs.

Operating theatres:

The operating theatre is a place where people are 'cut open' for one reason or another and is the place where cleanroom technology has its roots as I said. Yet very few, if any, operating theatres can be classified as a cleanroom. They are mostly a room with a unidirectional (laminar) air flow over the work area; outside this area the cleanliness level drops off, rather dramatically in some cases. OK, you might argue that the most important item, the patient, is in a clean area and yes I have to agree with that but what about all those items outside the clean area that are brought in later? They do not get clean simply because they are now inside the clean area. More to the point however, is that contamination control procedures in the operating theatres are often very lax and at some points non-existent.

Typically, I have seen theatre staff leave the theatre altogether to check up on some detail without changing and that includes the theatre shoes. Now, you will say that this is OK and how things are done but that does not make it right. From a contamination control point of view, this is a cardinal sin and after all isn't contamination control the whole point of the exercise?

Isolation wards:

My favourite...I have not seen one yet that cannot be described as anything other than a joke. You will say that this is a bit strong and that you have an excellent facility at your hospital, but do you? The idea of the isolation ward is to isolate a highly infectious patient or to protect immuno-suppressed patients and they will either be under a positive or negative air pressure according to the type of patient being isolated. So far so good.

The problem again is with the facility. They are generally built by people who have little understanding of the requirements of an isolation ward and maintained by people who have no idea about contamination control. The biggest problems I have come across are associated with HEPA filters, or rather the lack of HEPA filters. I repeatedly notice that there is a lack of HEPA filter testing where they are installed and a lack of any method of 'safe change' facility for the filters.

I will try to keep this simple. If a patient with a contagious disease is placed in isolation the object is to prevent the spread of the disease. The extract system will take the microbe laden air and discharge it into the surrounding environment but to prevent the microbes from getting out it is necessary to filter the air. HEPA filters are used for this purpose but those filters must be tested to prove that they are not leaking past their seals or that they are damaged, otherwise what is the point of the isolation ward? Furthermore, these filters are now contaminated and a 'safe change' facility is required to protect maintenance staff from the microbes.

Common sense yes? No! I could name one large teaching hospital where the above precautions are not met due to the costs involved and that is not an isolated case.

General wards:

While the other three areas can be classified as 'cleanrooms' even if loosely, the general ward is not a cleanroom; or is it? When we discuss cleanrooms *per se* it is often in the context of particle counts and BS EN ISO 14644 and the EUGGMP. Well that is alright for industry but a hospital is a very different place with the emphasis not so much on particle counts but on contamination control. Cleanroom procedures however are very good aids to contamination control, even when applied to an ordinary building such as an office, the home or the general hospital ward.

Look at MRSA for instance; it is extremely difficult to cure once infection has occurred so the problem is one of prevention, i.e. of contamination control. There are a number of cleaning agents that are effective against these microbes yet they are not widely used in hospitals. Why not? There are no effective contamination control procedures implemented in hospitals. Why not?

The root of the problem is that hospitals do not discuss their requirements with the right people. You talk to building contractors and air conditioning sub-contractors who do not fully understand (a) the requirements of the controlled environment and (b) that a hospital is, or should be, a controlled environment.

Cleanroom technology has come a long way since those early days and the science of contamination control has travelled with it. I suppose that my question shouldn't be has cleanroom technology left hospitals behind but rather, has the science of contamination control left hospitals behind?

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EN 1822 *continued*

EN1822 Filter Test Methods - Some Better Than Others:

Within the EN1822 standard there are three test methods.

Test Method 1 which is the main one, is to scan with a particle counter.

Test Method 2 is a single point volumetric test where you take all the air and measure it as a mixed homogenous mass some distance away.

Test Method 3 is Appendix A in the standard and is less than three-quarters of a page of text. It describes the paraffin thread test method. This may be used on H14, H13 and H12 filters which are common filters used in the pharmaceutical industry. As the test is visual it becomes very subjective. The manufacturer does not have to tell you which of the test method was used when marking up the filter.

The Hidden Cost:

The problem in the pharmaceutical industry is that risk management is often used when making the filter choice. As an example, if you are running a bottling station in an aseptic suite you are not going to be satisfied that the EN1822 tested H14 filter you have just purchased off the shelf from your supplier is allowed to have any number of 0.025% holes in the filter. A hole in the filter underneath your bottling station could be fatal, so you have to scan it. This risk is otherwise too high. Currently when you go out to buy a filter for pharmaceutical applications you have to specify how to test the filter. If you accept the EN1822 test methods, you could end up with a filter with holes in it. It has been a major problem and a huge cost to the industry because filters have been installed only to find that they have to be removed again because they are not suitable for the application. The costs to the country are huge because of that - when it could all be avoided!

Neil Stephenson

FUTURE OF ENVAIR SECURE

Envair, one of the UK's leading manufacturers of specialist healthcare and pharmaceutical equipment is under new ownership.

Now the future of Envair is looking bright after a new company established by the shareholders of medical equipment manufacturer AFOS purchased the business and assets of the company which went into administration in March. The new company will take the name Envair Limited.

AFOS shareholder Mike Sutton who led the purchase said: "We are delighted to have purchased the assets of Envair.

Envair has built up an excellent reputation and had been trading successfully for more than 30 years.

"Envair Limited will be a complimentary fit with AFOS and will benefit greatly from our position in global healthcare and pharmaceutical markets."

Envair Limited, will continue to trade separately at Haslingden, Lancashire. It specialises in providing clean air and containment facilities for healthcare, laboratories, pharmaceutical and industry.

AFOS has a global reputation for the design and manufacture of quality stainless steel medical equipment such as pathology tables and mortuaries.

Together the two companies will have a combined turnover of more than £12m and employ 100 staff.

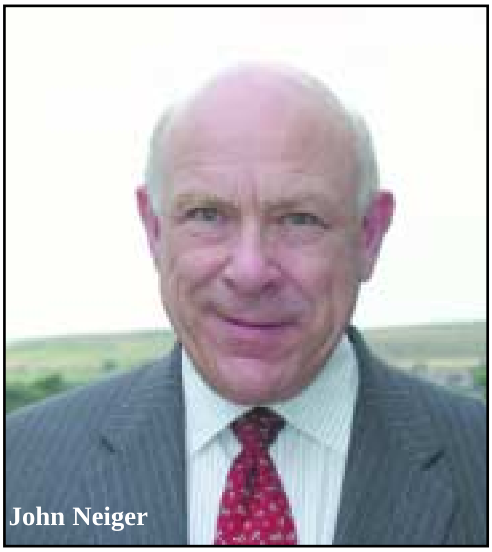
Mr Sutton who is Executive Chairman of Hull based AFOS added: "There is a synergy between the two companies which will bring many benefits to both companies and to our respective clients.

"The combined strengths of AFOS and Envair will provide a powerful proposition for our clients and will enable us to increase our market penetration and increase profitability for both companies."

ISO 14644 Part 6

It is now being proposed that ISO 14644 Part 6: 'Terms and definitions' be reinstated in the work program of ISO/TC 209. John Neiger has agreed to be the nominated UK expert to the working group - WG 6.

This role was previously held by Neil Bell and John considers it a significant honour to be succeeding such a distinguished predecessor.



John Neiger

CLEANROOM TESTING COURSES

A one day course on Cleanroom Testing is being given at the Erskine Bridge Hotel near Glasgow on Wednesday, June 23, 2004 (Registration 8:30 - 9:00 am)

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

Cost: per delegate including lunch and tea/coffee is

Members: £145 + VAT (£170.38)   Non-members: £162 + VAT (£190.35)

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 22-24, 2004. However, the course is fully booked as is a similar course being run in Dublin on November 9-11, 2004. These courses which started 2 years ago are now being offered in Sweden and Ireland. See Issue 48.

Future Courses: No dates are confirmed but the following information may be of interest.

If you want CTCB certification then it is the 3 day CTCB course	**If you do not want CTCB certification then it is the 1 day S2C2 course**
Registration To attend the course, registration is essential as candidate suitability is assessed.	**Registration** Contact S2C2 office to obtain a course brochure and application form.
Eligiblity This course is for people who test cleanrooms either daily or regularly. There are 2 levels: professional or associate.	**Eligiblity** 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 Registration is £100 + VAT. This covers the course and Question and Answer manuals. The couse fee is £560 which includes a one day practical training course.	**Cost** Members: £145 + VAT (£170.38) Non-members are required to pay an additional £17 + VAT See above for June 23, 2004.
Examinations Two - theory and practical.	**Examinations** None.
Certification On successfully passing both exams a certificate is awarded.	**Certification** A certificate of attendance is issued.

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

YELLOW GUIDE

PHARMACEUTICAL ISOLATORS
A GUIDE TO THEIR APPLICATION, DESIGN AND CONTROL

1st edition *

Edited by: Brian Midcalf, W Mitchell Phillips,
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** This is the new edition of the Yellow Guide (Also see additional information in Issue 49.)*

ERRATUM
The new Yellow Guide is published by Pharmaceutical Press not Pharmapress as stated on page 1 of Issue 49.

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