

S2C2

THE CLEANROOM

# MONITOR

## The Scottish Society for Contamination Control

May 2001

Issue 42

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### CLEANROOM GARMENTS

by  
NIGEL SLATER

Tuesday, June 5, 2001  
Erskine Bridge Hotel, Erskine, Near Glasgow

- Do you know how to select the appropriate garments for operators to wear in the cleanroom?
  - Are you aware of the different types of materials available?
  - Do you understand the different properties required from these materials?
- If the answer is NO to any of these questions then you should attend this course.

#### Programme:

12:30 - 1:30	Lunch and Registration
1:30 - 2:30	Lecture
2:30 - 3:00	Tea/Coffee
3:00 - 4:00	Lecture

#### Course Content:

- the materials used to construct cleanroom garments
- the properties of these materials
- the construction of garments
- the testing of materials and garments
- advances in technology

Contact: S2C2 office. Details on the left.

## DATALOGGERS

Dataloggers can be used to measure and record a wide range of parameters including temperature, pressure, humidity, voltage and current.

In some applications, fixed instrumentation may only provide limited information based on measurements taken at a particular point while for others it may not be practical to install permanent instruments. Therefore data loggers play an important role in monitoring and recording data in a wide range of industries.

In the past, data loggers have tended to be relatively bulky devices which often needed to be powered via the mains supply or large battery packs, restricting their use to permanent or semi-permanent installations. Significant developments in low power electronics and battery technology have enabled manufacturers to design smaller and smaller portable data loggers and as a result, their use is increasing across a broad spectrum of industries. Portable loggers typically are comprised of signal conditioning electronics, one or more sensors (either internal or external), built-in memory unit, clock and internal battery. Unit configurations include: *single channel*, *multiple channel - single parameter* or *multiple channel - multiple parameter* (for example temperature and humidity, or temperature, humidity and pressure).

One of the most important aspects of their design is the method used to communicate with the logger in order to carry out set up and to extract data. This is usually carried out in conjunction with a PC or laptop computer using dedicated software. There are three main methods used: direct cable link, infra red and induction. The latter two do not require any form of electrical connector or the sealing; integrity is assured. This is vitally important in harsh environments such as the food and chemical industries.

In order to conserve battery life, loggers use special low power electronics and can be set up to measure and record at discrete pre-set periods. Depending on the application, sample rates are usually set anywhere between several times a second up to several days and therefore the total logging period is a function of this period and the internal memory size. Depending on the design and set-up, data may be stored until the memory is full (fill then stop) or stored on a continual basis with the older data being automatically replaced (first in- first out).

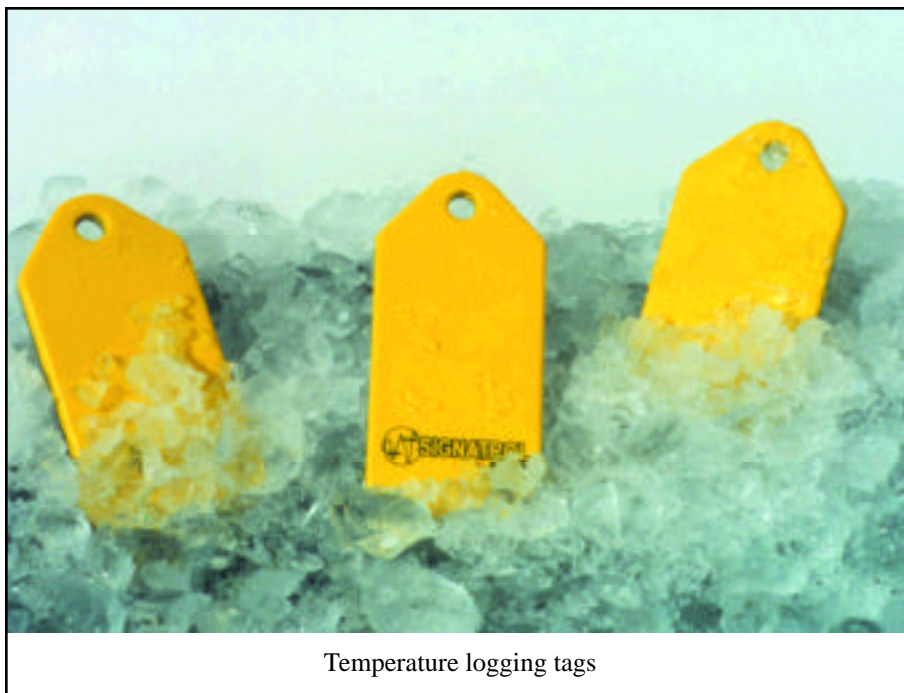
The key to successful datalogging is being able to place the logger right at the heart of where the parameter has to be measured. When selecting a logger for a particular application, consider: measurement range, number of

measuring channels, environment and sealing requirements, setup and downloading of data, security, size, logging period, reading frequency and storage memory, logger placement and retrieval.

### Temperature Datalogging

The logging of temperature represents one of the widest uses for data loggers with applications as diverse as monitoring blood product transportation for the British Armed Forces, the manufacture of compost from sewage sludge and recording temperature profiles in bread ovens and industrial washing machines. The reasons for datalogging are equally diverse and include product or process verification, traceability and long term environmental research.

Temperature loggers are ideal for checking temperature profiles and find application in areas such as museums, art galleries, environmental chambers, vehicles, ovens and freezers. Depending on the application, either a number of



Temperature logging tags

individual loggers can be used or single units with multiple sensors. Individual units have the advantage of being compact, discrete and easy to place. For certain applications loggers with combined humidity and temperature sensors provide important environmental information.

The flexibility of the data loggers can be radically extended by the use of thermal barrier boxes, which allow the loggers to operate at temperatures up to 350 degrees C. The loggers are kept insulated and sealed inside the barrier's stainless steel box while external sensors measure the temperature. This arrangement is ideal for oven temperature profiling to provide documentary evidence that products are reaching and maintaining the required cooking temperatures. The barriers can travel through the oven with the food. The data can also

# DATALOGGERS

be used to optimise cooking times thus maximising throughput. The barrier units are equally suited to use in chillers, spiral freezers and blast freezers.

## Safety and Traceability

With heightened awareness of issues relating to safety and quality of a wide range of perishable products and goods, increased legislation is leading to the implementation of new procedures and controls for storage and transportation. As equipment and systems become more sophisticated, the opportunity for error or fraudulent misuse increases and therefore unambiguous and strict product traceability systems are vital.

Temperature control is one of the most critical factors in ensuring the quality of perishable goods such as food, drugs, medical products and pharmaceuticals, especially during transportation. Routings can be complex with goods often being transhipped using several different methods and carriers.

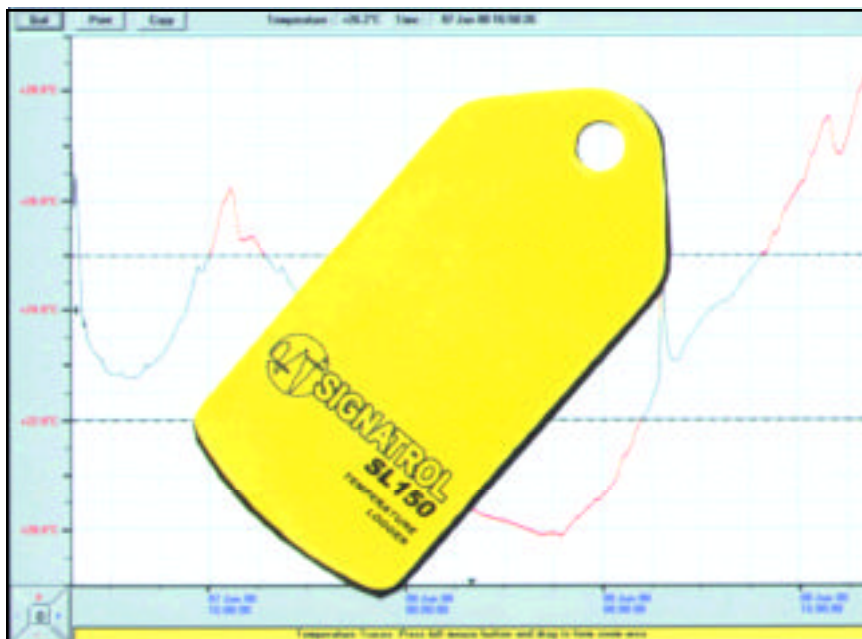
Direct monitoring of the temperature of the product is infinitely more reliable (and hence more diligent) than the general monitoring of the environment inside vehicles and containers. The important factor is that compact portable loggers can monitor the total journey even when this involves several stages of responsibility.

Consider the example of beans picked fresh in Zimbabwe. These must be transported swiftly to the field picking station, washed, graded and then packed. From here they are transported to the airport, airfreighted to the UK, transhipped on to the supermarket distribution centre and then on to the individual stores.

When a major supplier in Zimbabwe was faced with claims for premature food deterioration, they needed a simple yet effective way of finding the source of the problem. Analysis of the data over a few weeks highlighted that sometimes the temperature of the produce was rising above acceptable levels. The data gave clear information on when this had occurred and it was not difficult to identify that this coincided with the time when the produce should have been airborne on its way to London. However checks with the airline at Harare airport showed that flights were regularly delayed. Planes could sit on the runway in searing heat for up to two hours and this caused the consignment to heat up. The produce is now packed in insulated containers and this has solved the problem.

One of the strangest arose when a fish processing company were having problems with their cold stores. Engineers carried out thorough checks on the equipment and could find nothing wrong. However the problems continued and the

company decided to place a number of datalogger tags inside the rooms. Analysis of the data showed that on Sunday the temperature went above the company's tolerances. A special watch on the cold store revealed that on Sunday the company's account clerk would come into his office to catch up with his paperwork. This happened to be located next to the cold store plant room and he turned off the refrigeration system so he could concentrate on his work!



## Conclusion

Portable data loggers present powerful tools for monitoring and validating parameters in a wide range of processes and environments. Data can be used for simple checking of permanent instrumentation and controls through to more complex validation processes and even litigation and insurance claims. Their applications will continue to grow as demands from users increase. As well as their use in storing physical data these products are also being used in applications as diverse as monitoring operator efficiency on production lines by measuring pulses from proximity switches to providing data for management.

\* **Author:** David Green, DCG Associates, 24-26 Nursery Grove, Kidderminster, DY11 5BG. Tel 01562 638 800 Fax 01562 638 170. [www.weighing-systems.com](http://www.weighing-systems.com).

**SL-150 dataloggers:**

Signatrol (A division of Status Instruments Ltd)  
Green Lane Business Park  
Tewkesbury  
Glos, GL20 8DE  
[www.signatrol.co.uk](http://www.signatrol.co.uk)  
Tel. 01684 296 818

## WEB FORUM - CLOTHING & PARTICLE DISPERSION

### SUBJECT: Microbial Dispersion by Clothing

This may sound naive, but I am trying to find info on the number of organisms (both viable and dead) the average human body releases per unit time, and under a range of circumstances, e.g. relaxed vs. highly stressed, temperature dependencies, etc.

How well is this contained in the field and in the lab, that is, what kind of leakage is there for low and high end containment systems, technologies, processes?

For example, presumably suits leak a bit, how much?

[ML]

### ONE RESPONSE:

Your question is not naive but cannot be fully answered. There is very little information on microbial dispersion from people. We know that people give off from less than 10 to over 20 000 microbe-carrying particles per minute. These are skin particles with microbes on them. The dispersion rate is in proportion to activity but I do not know of any exact relationship.

Clothing reduces dispersion. The more layers you have on, the less dispersion. The design of clothing is important; the more you envelope someone the less dispersion there is. A full coverall-system could be 10 times better than a gown as bacteria come out from underneath the gown.

The fabric is important as the pores in the fabric can be as large as over 100 micrometres. Microbe-carry particles are in the area of 20 micrometres. Good clothing with good closures at neck etc. can reduce dispersion by about 100 times.

You ask about temperature. I have no scientific evidence but I have observed a reduction in dispersion when a person get hot and sweats: this would seem reasonable as the skin cells would not disperse into the air as easily.

If you can get the following paper, it might be of some interest:

### REFERENCE:

Reduction of Microbial Dispersion by Clothing. W Whyte and PV Bailey. *Journal of Parenteral Science and Technology*. Vol 39, 51-60.

[WW]

### SUBJECT : Cleanroom Gowns - Preparation

Sterile (that is irradiated) verses adequately sanitised (chemical sanitisation) are both acceptable according to EU GMP Annex 1. I would welcome any comments on the suitability of the two methods of preparation of clean room gowns.

My view is that chemical sanitisation is preferable. Although it offers a lower assurance of sterility of the garments per se, it reduces damage to the garments and ultimately provides better protection for the product over the lifetime of the garments.

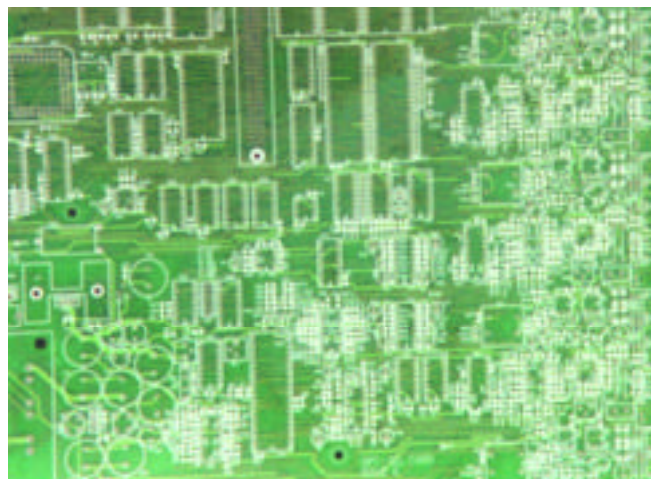
[BH]

### ONE RESPONSE:

I support your thought that chemical disinfection is the best choice for processing cleanroom clothing for the pharmaceutical and similar industries. I have been associated with both a cleanroom laundry that has carried out this process for many years, and a pharmaceutical company that used such garments for many, many years. There was never any problems. I cannot say the same about garments that were sterilised, and have heard of several problems caused by excessive deterioration in the fabric.

I would also remind you, and anyone that reads the *Cleanroom Forum*, that bacteria dispersed by people come from their skin and pass through their garments. Very few come from the garment's surface. I have shown, in a body box, that a person wearing a dirty garment, made from a tightly-worn fabric, will disperse less than a bacteria-free one made from a poor fabric.

[W W]



## WEB FORUM - CLEANROOM GARMENTS

### SUBJECT: Helmke Drum Procedure

What is the recommended particle count at 0.5 micron for Integrity 2000 garments after the Helmke Drum Test? What is the acceptable range?

#### ONE RESPONSE:

Presented below are Helmke Classifications for particles 0.5 microns and larger. Please go to [www.iest.org](http://www.iest.org) and obtain a copy of **IEST-RP-CC003.2** for a full presentation of the Helmke Drum Procedure and Cleanliness Classifications.

Other relevant information may also be found in the Recommended Practice including cleanliness classifications for 5.0 micron particles and fibers per ASTM F51-68, body box, etc.

Category I for 1 medium coverall is less than 1,200

Category I for 1 medium frock is less than 1,000

Category I for 3 hoods is less than 450

Category II for 1 medium coverall is 1,200 to 12,000

Category II for 1 medium frock is 1,000 to 10,000

Category II for 3 hoods is 450 to 4,500

Category III for 1 medium coverall is 12,000 to 120,000

Category III for 1 medium frock is 10,000 to 100,000

Category III for 3 hoods is 4,500 to 45,000

[CB]

#### EXCUSE ME, BUT...

When I read the classification chart, how do I know which category to look at? Can you briefly describe what each category refers to?

Which category refers to Integrity 2000 garments used in Class 1 environment?

Also, does ISO 14644 Class 3 correlate to 209E Class 1 M1.5? I am trying to understand this standard so we can convert to its usage.

#### ANSWERS:

Contribute to this thread by logging on to the Cleanroom Forum website at [www.s2c2.co.uk](http://www.s2c2.co.uk).

### SUBJECT: Evaluation of Garments

I have gone through TGA and ASTM standards which says to check garments microscopically for particles and fibres. Based on the results, the garments are classified for use. But are there any other methods to evaluate the cleanroom garments?

In fact we do not have facility or testing lab for determining the pore size of the garments. Only we could do is to determine the air flow across the garments.

Can we correlate it with pore size or determination of filtration efficiency of the garments?

Can operator's comfort be determined from such tests?

[M]

#### ONE RESPONSE:

Go to [www.iest.org](http://www.iest.org) and get a copy of IEST-RP-CC003.2. Comfort is determined by measuring Moisture Vapor Transmission Rates (MVTR) - See ASTM E96-80.

This test is entitled "Test Methods for Water vapor transmission of Sheet Materials" but is used to ascertain garment/fabric comfort. Check with your local cleanroom garment/fabric supplier, they will educate you.

[CB]

**Need to know more?**

**S2C2 course**

**CLEANROOM GARMENTS**

by

**NIGEL SLATER**

**Tuesday, June 5, 2001**

**Erskine Bridge Hotel, Erskine,  
Near Glasgow**

**To book, refer to front page.**



## ADVERTISING on the S2C2 WEB SITE

The Services and Products section of the S2C2 site is receiving over 1500 hits a week from people looking for specific services. As a member of S2C2 you can make your name stand out by placing a banner advert in this section. As a non-profit-making organisation we offer this at a fraction of the cost on other similar sites.

Advert level	Insertion place	Cost/annum
Level 1	On first page of 'services and products' section	£1000 + VAT
Level 2	On top of first page of category of service	£500* + VAT
Level 3	Next to your individual advert	£250* + VAT

\* there is a 30% discount for additional adverts on this level.

We have set up a sample page layout. If you enter [www.s2c2.co.uk/spadsim/snp/html](http://www.s2c2.co.uk/spadsim/snp/html) you will see the sample advert's place at the three levels described in the table.



We will only insert standard Internet layouts of the types shown in the example pages. These files must be a max of 12K, either 450 x 60 or 125 x 125 pixels maximum, and in GIF format.

You can provide ready-made files, or our Webmaster can produce such adverts for you at a reasonable price. Contact him -



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## CHAIRMAN'S CORNER

Hello members of S2C2 !

I hope you enjoy this edition of *The Cleanroom Monitor*.

The Executive Committee and I are currently planning lots of exciting events for the forthcoming months - courses, developments on the website, site visits etc. so keep in contact with us if you don't want to miss out on anything.

Training of all persons involved in Cleanroom Technology is of paramount importance and we hope to address some of the burning issues we know you have either by the Cleanroom Question and Answer Forum on the website or by appropriate courses. However we can only do so much. You - the membership - must help us by telling us what you need in terms of teaching and information!!

At present I have a burning issue with the level of training Validation and Commissioning companies give their engineers. As we manufacture pharmaceuticals in our cleanrooms and isolators and as our customer is the patient, I must have the utmost faith in the ability of the engineers coming on site to carry out testing. No other product is consumed so much on trust and therefore it is imperative that testing is carried out correctly. This is just not happening. As most of the companies use different methods for testing, the equipment they use sometimes looks as if it came from the ark and calibration certificates are not always available.

I think it is about time that improvements are made and I welcome comments on this issue. **Lynn Morrison, Chairman**



### ERSKINE 2001



Peter Smith of Marconi Casswell with his Cleanroom Validation certificate.

### AUTUMN 2001

**AGM,  
Conference and  
Exhibition  
AUTUMN 2001  
Date to be announced**

## ALFRED NOBEL AND ARDEER

In a manufacturing situation one of the paramount keys to safety is the appreciation of the hazards involved at each stage of the process. In the field of the chemical industry there is nowhere more fully appreciative of this tenet than the explosives industry where the consequences of failure can be disastrous. The account of Alfred Nobel's early experiences is a classic example of how concern of cleanliness in the workplace to avoid impact and friction led to the invention of the modern safety explosives of today.

This 70-page book is concerned mainly with the early years of the Ardeer Factory [1871 to 1896]. Most of the account is drawn from unpublished personal memories and notes of members of staff who knew Nobel and worked with him during the early days or knew members of staff who did and were able to record their accounts and reminiscences.

Imperial Chemical Industries, in 1926, arose out of the commercial success of the Dynamite company that Alfred Nobel established in Scotland. Nobel, originally from Sweden, was the inventor of Dynamite, Gelignite and the detonator. He came to Scotland in 1871 and set up an explosives factory on a spit of land on the Ayrshire coast at Ardeer, north of Irvine. Today he is perhaps mainly known for the Nobel Prize. But his curiosity and inventiveness in relation as to how the highly sensitive and dangerous nitroglycerine, which had been around for some years, could be safely used for industrial explosives transformed civil engineering, mining and quarrying into the high technology industry it is today.

In the 1860's Nobel began manufacturing nitroglycerine commercially in Sweden, marketing it as "Nobel's Blasting Oil". However the use of nitroglycerine in its liquid form was accompanied by a series of tragic accidents in transport and use including an explosion in 1864 where his youngest brother was killed. Nobel tried many experiments to improve the degree of safety in handling the chemical. He finally tried combining nitroglycerine with Kieselguhr or Fuller's Earth. This consists of the skeletons of the minute sea creatures, diatoms, and has the ability to absorb many times its own weight of oil. Nobel found that it was capable of absorbing 4 times its own weight of nitroglycerine giving a red powder which was safe to handle. He called this mixture after the Greek word for power "dynos" and the base diatomite [from the sea creatures, diatoms] giving Dynos Amite or Dynamite. He knew he was on to a winner. He knew this powder, unlike the highly sensitive liquid nitroglycerine, could be safely cartridgeed into preformed paper shells. Putting this invention along with his invention of the detonator he gave the world the key to a new era of powerful controlled blasting explosives. The success of the invention was almost instantaneous but there were those who had been using



Overshoes - a clean floor but a trap for the unwary visitor (1900)

Nobel's Blasting Oil who felt they were being shortchanged because Dynamite only contains 75% nitroglycerine whereas Blasting Oil was 100% nitroglycerine. So Nobel carried his concept one stage further. He replaced the inert Kieselguhr with active Nitrocotton and invented the completely waterproof explosive, "Blasting Gelatine" with no inert material. This explosive is still today the most powerful commercial explosive available and is used as the standard against which all other explosives are judged.

Nobel set up dynamite companies in Sweden, Finland, Germany and Norway before turning his attention to Great Britain, the rest of Europe and the U.S.A. By this time, 1865, he had taken out a British Patent for Dynamite. However, the reputation

of liquid nitroglycerine preceded Nobel when he tried to convince people in the UK of its potential. The government would not be convinced that Dynamite was safe to use. He tried for 2 years. He got a reluctant easing of strict regulations but was unable to obtain permission to establish a business in England.

He turned to Scotland where he found a receptive group of entrepreneurial Glasgow businessmen in the Clyde Shipbuilding field. But he needed to find a location, which would meet the approval of the central authorities. He obtained 100 acres of land, mostly sand dunes, from the Earl of Eglinton's Ardeer estate on the Clyde Estuary and permission to build a dynamite factory was eventually granted. He set up The British Dynamite Company in 1871.

Nobel's first impressions of Ardeer are succinctly expressed in a letter to his brother in which he states:

"Picture to yourself everlasting bleak sand dunes with no buildings. Only rabbits find a little nourishment here: they eat a substance, which quite unjustifiably goes by the name of grass. It is a sand desert where the wind blows often howls filling the ears with sand. Between us and America there is nothing but water a sea whose mighty waves are always raging and foaming. Now you have some idea of the place where I am living. Without work the place would be intolerable."

Nobel moved to the area in 1871 later establishing residence in Lauriston near Falkirk. Construction of the plant on the "greenfield site" at Ardeer took 2 years. Roads, huts, packing houses all had to be built. All the houses in the nitroglycerine and cartridge-making departments had floors of sand. The Home Office agreed that a heavy layer of the fine sand from the dunes would not constitute grit in the sense of the Explosives Act of 1875! The top layer of sand on the floors was periodically removed (as it was unavoidable that some explosive should find its way into it) and replaced with fresh

# EXPLOSIVES

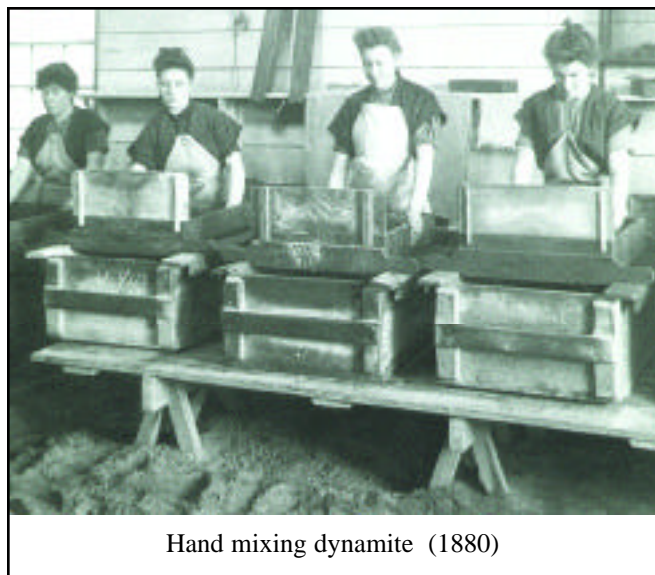
sand from the more plentiful local supplies.

One drawback of the sand dunes was that the strong storms would lift the fine sand and deposit it in all sorts of places. In the laboratory, for instance, after a night's storm, one would find a fine sprinkling of such sand on tables and apparatus causing no end of nuisance (and potential hazard!)

The dunes did serve one useful purpose however in that they were very suitable for the building of explosives processing houses and magazines in so far as these could be placed in the natural sand hollows, thus avoiding or reducing the expense of erecting special bunkering embankments.

Even in these early the dress routine was strict. No metal of any kind was allowed. A serge uniform devoid of buttons or fasteners was obligatory. Even hairpins were forbidden (in case they fell into the mixer and created an impact hazard) and special precautions had to taken to exclude any foreign material being in or taken into the process houses.

All the girls in the factory worked in bare feet, although this was not compulsory. It was, however, soon appreciated that



Hand mixing dynamite (1880)

the official relaxed attitude towards sand floors was much mistaken and a regime of "clean floors" and walkways was introduced. Occasional visitors to the operations had perforce to wear "Overshoes" or "Polar Boots" on top of their normal footwear to prevent contamination of the "clean floor".

The awkwardness of this footwear was admirably described by one visitor in the following terms: -

"Yawning rubber shoes have to be worn in all departments and the girls are compelled to change to slippers or to work barefooted, the majority, in summer, preferring the latter. The over-shoes are really trying, particularly as you have other things to worry you. Snow shoes, ski and stilts can be practiced on with considerable advantage before you endeavour to get about in a pair of these over-shoes which invariably do not fit your own shoes, and are ceaselessly trying to trip you up and often succeeding."

Quality testing of the cartridge product was intriguing. A sample of the cartridges from each house was collected by the foreman with the cartridge girl's name written on the

wrapper. The cartridge was then unwrapped and dropped into a large glass beaker full of nitroglycerine and a note made as to whether it "swam" or "sank". The cartridges were divided into 2 classes: "swimmers" or "sinkers". To be of acceptable quality the cartridges should sink. The girls who produced "swimmers" were warned to put on more pressure in forming the dynamite into cartridges.

This concern about clean floors and non-impact non-friction equipment was paramount. A concern which dominates the safety ethos of the industry through to the present day particularly in handling the sensitive nitroglycerine before it is made safe in the mixed explosive. The nitroglycerine is transported in rubber-lined buggies constructed of wood with rubber-tyred wooden wheels called "Angel Buggies" (for obvious reasons). The floor of the nitrating house and on which the buggies run is lead to minimize impact and friction and which is kept washed down to remove any grit or other foreign material. There can be no foreign metal which could be a frictional or impact hazard in the building, clothing or shoes.

Tremendous changes have taken place in the 130 years since Nobel first produced Dynamite at Ardeer and many lessons have been learned not the least that no aspect of cleanliness can be ignored. For example a great deal of research has been carried into the safety of the materials of construction used by the engineers who design and build the specialist processing machinery again using sensitivity to impact and friction as the criteria. A small sample of the explosives under test is placed on an anvil of the material under investigation and a drop hammer allowed to impact the sample from different heights (therefore of different kinetic energies) The materials of the anvil and hammer are varied and the sample is adulterated with different sample of grit and dust to determine the effect of foreign material on the safety of the manufacturing process. These studies guide the engineer and the plant hygienist in the precautions to take in both construction and plant cleanliness.

The "leave no stone unturned" philosophy of safety applies throughout the whole of processing with an added dimension in manufacturing detonators where static electrical discharges have to be avoided. This again affects the choice of materials of construction, and involves the use of conducting and earthed floors and scrupulously clean operating conditions. Here, even the wearing of nylon with its static hazard is forbidden!

*The author, John Dolan, joined ICI in 1948 after service in the army and was involved in research and later in the marketing of explosives. He was a Director of the German Company Wano Swartzpulver from 1977 until 1979 then a director of Irish Industrial Explosives until 1982. He retired in 1984 but continued as Secretary General of the European Federation of Explosives Manufacturers until 1994. He was awarded the Queen's Silver Jubilee Medal for services to industry in 1977. His wife Mary Theresa was the assistant librarian at Ardeer and to whom the book is dedicated.*

See also: Dr Mark G Shilton, Static Electrification, April/May 2001 *Cleanroom Technology*, page 31-32.

## DECEMBER 2000 UPDATE FROM BRITISH STANDARDS

### International Standards

Cleanroom standards being produced for world use by the International Organization for Standardization Technical Committee 209 are progressing. The defined development stages carry prefixes as follows:

**WD: Working Draft.** Circulation of developing document within the Working Group set up by the ISO/TC209 Committee.

**CD: Committee Draft.** Circulation of approved Working Draft within ISO/TC209 for approval and or comments by the National Technical Bodies of the participating countries (British Standards Institution in the case of the UK).

**DIS: Draft International Standard.** Circulation of the ISO-approved Committee Draft by ISO for public enquiry in all ISO member countries.

**FDIS: Final Draft International Standard.** Circulation of approved DIS for final vote.

These ISO/TC209 documents are at the stages described:

**ISO 14644-1:** Cleanrooms and Associated Controlled Environments, Part 1: Classification of air cleanliness. ISO 14644-1: 1999 has been published.

**ISO 14644-2:** Cleanrooms and Associated Controlled Environments, Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1. **ISO 14644-2:2000** has been published.

**ISO 14644-3:** Cleanrooms and Associated Controlled Environments, Part 3: Metrology and test methods. This draft has been issued as **CD 14644-3**.

**ISO 14644-4:** Cleanrooms and Associated Controlled Environments, Part 4: Design, construction and start-up. This draft is in preparation for issue as **FDIS 14644-4**.

**ISO 14644-5:** Cleanrooms and Associated Controlled Environments, Part 5: Operations. This draft has been issued as **CD 14644-5**.

**ISO 14644-6:** Cleanrooms and Associated Controlled Environments, Part 6: Terms and Definitions. Document under development.

**ISO 14644-7:** Cleanrooms and Associated Controlled Environments, Part 7: Separative enclosures (clean airhoods, gloveboxes, isolators, minienvironments). This draft is in preparation for issue as **CD 14644-7**.

**ISO 14698-1:** Cleanrooms and Associated Controlled Environments, Biocontamination Control, Part 1: General principles. This draft - approved for issue as **FDIS 14698-1**.

**ISO 14698-2:** Cleanrooms and Associated Controlled Environments, Biocontamination Control, Part 2: Evaluation and interpretation of biocontamination data. This draft has been issued as **DIS 14698-2**.

**ISO 14698-3:** Cleanrooms and Associated Controlled Environments, Biocontamination Control, Part 3: Methodology for measuring the efficiency of processes of cleaning and (or) disinfection of inert surfaces bearing biocontaminated wet soiling or biofilms. This draft has been issued as **DIS 14698-3**.

### Drafts issued by BSI for public comment in UK

The present situation is as follows.

**CD 14644-4:** Public comment terminated on 27th March, 1997 but the Draft is still publicly available. **DIS 14644-4** has also been issued and is available on request. No further comments on this draft will be accommodated.

**CD 14698-1:** Public comment terminated on 30th November, 1996 but the Draft is still publicly available. **DIS 14698-1** has also been issued and is available on request. Any further comments received at this stage may not necessarily be accommodated.

**CD 14698-2:** Public comment terminated on 30th November, 1996 but the Draft is still publicly available. **DIS 14698-2** has also been issued and is available on request. Any further comments received at this stage may not necessarily be accommodated.

**CD 14698-3:** Public comment terminated on 30th November, 1996 but the Draft is still publicly available. **DIS 14698-3** has also been issued and is available on request. Any further comments received at this stage may not necessarily be accommodated.

### European Standards

**ENV 1631: 1996:** Cleanroom Technology: Design, construction and operation of cleanrooms and clean air devices. This is a published European pre-standard available from BSI as **DD** [Draft for Development] **ENV 1631: 1996**. It will be superseded when 14644-4 and 14644-5 are published.

**ISO 14644-1:** 1999 and **ISO 14644-2:2000** have been implemented as **EN ISO 14644-1: 1999 & EN ISO 14644-2** respectively, for publication by the national standards bodies that are members of CEN (see below for United Kingdom). **DIS 14644-2**, **DIS 14644-4**, **DIS 14698-1**, **DIS 14698-2** and **DIS 14698-3** have also been issued in parallel by CEN as **prEN ISO 14644-2**, **prEN ISO 14644-4**, **prEN ISO 14698-1**, **prEN ISO 14698-2** and **prEN ISO 14698-3** respectively.

### British Standards

**EN ISO 14644-1: 1999** and **EN ISO 14644-2:2000** have been published in the UK as **BS EN ISO 14644-1: 1999** and **BS EN ISO 14644-2:2000** respectively. **Parts 1 and 4 of BS 5295** have been withdrawn, while **Parts 0, 2 and 3 of BS 5295** were amended in 2000. A revision of **PD 6609** was also published in 2000. **PD 6609:2000** contains some of the original content of **BS 5295-1:1989**.



Submitted by Neil Bell who is the S2C2 nominee to represent the UK on the group of ISO Standards dealing with cleanrooms. He is Secretary of Working Group 6.

Obtain publicly available documents from: BSI Standards, 389 Chiswick High Road, London, W4 4AL.

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## PROFILE - Susan Branigan

In a recent Cleanroom Validation seminar hosted by S2C2, Bill Whyte observed that when a cleanroom is built or modified, certain basics must be addressed: among them, testing, benchmarking, and perhaps most importantly, training the staff in correct procedures of cleanroom operation.

Susan Branigan could not agree more! Recently, she has set up her own business to do just that - train cleanroom personnel.



She has been involved with cleanroom manufacturing for over 10 years, starting off in the Medical Device industry, and quickly getting more directly involved in the sales and supply of cleanroom consumables, to a broader cross-section of industries. "Sales was only supposed to be a short spell in my career ladder", Susan admits, " before I went back to University to do a teaching diploma...(from Dublin, she studied in University College Galway, in the West of Ireland, for an Arts Degree) but somehow, the Cleanroom industry took hold, and enticed me to stay."

When employed by a leading healthcare multinational organisation, Susan was sent to the USA on several occasions for in-depth cleanroom training. Working in partnership with major global semiconductor companies in Ireland gave her a great basis of understanding of the cleanroom philosophy and principles.

When, in 1998, fate intervened, in the form of a Scottish husband-to-be, and transferred her to Edinburgh, Susan took up where she left off, this time covering an area of Scotland and parts of North / South of England. Having been warned

to expect a very different market and customer base, she set out on the motorway, to see what awaited.

In fact, the welcome was as warm as any she ever encountered in the Green Isle. Coming to the UK also gave her the opportunity to practice more of her original interest - teaching, albeit in the form of training, to colleagues and customers alike, about the cleanroom and products used.

On her travels, Susan became increasingly aware of companies asking about this area; people who were short staffed, or didn't have the time to train their new or even existing operators and cleaners; people who were aware that there is always room for improvement, if they just could get the resource.

Susan believes she has the answer - with several training courses on offer as well as consultancy, she works with her clients to customise the cleanroom solution/package. Her vision is to pass on her knowledge of cleanrooms, at a practical level, so that more cleanroom personnel will have greater understanding of their working environment; thereby being more comfortable in themselves, but also contributing to a better quality of environment, more efficient cleaning routines, and improved product yield.

After 10 years in the sales side of the industry Susan hopes that her new business venture will now help give something back.

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