Management Forum bio-safety and bio-security conference

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This two day conference, held at the Rembrandt Hotel in London on 8th and 9th March, attracted speakers and delegates of the highest quality. Conferences on this subject are infrequent; indeed this is the first one in the UK that I have been aware of in nearly forty years in the industry. The conference was very ably chaired by Gordon Farquharson, of Critical Systems Limited, who combines a friendly and effective chairing style with an impressive knowledge of all aspects of the subject.

The first talk was by Steve Copping, Head of Compliance, Regulatory Affairs and Risk at the Institute for Animal Health, Pirbright Laboratory, UK. Steve started by describing the existing premises at Pirbright and the ambitious plans for a world-class facility planned – hopefully – to open in 2013-14. A dramatic early slide showed all recent major incidents of newly emerging, re-emerging/resurging and 'deliberately' emerging (i.e. bio-terrorism) disease against a world map. Global outbreaks of infectious disease present a growing concern internationally and approximately 75% of emerging diseases are zoonotic (transferable from animals to man and vice-versa). Therefore laboratories, such as Pirbright, are required internationally to strengthen disease surveillance, prevention, control and response. The WHO International Health Regulations are legally binding under international law and all 193 WHO member states must reach a minimum level of surveillance and reporting capabilities by 2012. A key tool in achieving the necessary standards in laboratories is CWA 15793:2008 – Laboratory Biorisk Management Standard. A CWA (CEN Workshop Agreement) is a less formal document than a full CEN standard, less prescriptive also, but no less useful. CWA 15793 is a 'plan-do-check-act' type document and sits well with ISO 9001, ISO 14001, ISO 16001 and ISO 18001. CEN Workshops 55 and 53 are developing further guidance documents on, respectively, the implementation of CWA 15793 and Biosafety Professional Competence to support CWA 15783. The aim is that laboratories be certified to the CWA to achieve international trust and recognition.

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The next talk, by Phil Greaves of Bovis Lend Lease Consulting, was on IEC 61511 – Functional safety. Safety instrumented systems for the process industry sector. Framework, definitions, system, hardware and software requirements. This standard is the process implementation of IEC 61508 – Functional Safety of Electric/Electronic/Programmable Electronic Safety-Related Systems. There are other implementations for nuclear and manufacturing. IEC 61511 is published in the UK as BS EN 61511:2004, in Continental Europe as EN 61511:2004 and I the USA as ANSI/ISA 84.00.01-2004. All three are identical except that the ANSI/ISA version has a very helpful 'legacy' clause which allows an existing system, built prior to the standard, to be used provided it can be shown to be safe. In the UK the standard was adopted by the HSE for bio-containment laboratories following the 2007 Foot and Mouth release. Key concepts in the standard are Safety Integrity Levels (SIL), Safety Instrumented Systems (SIS) and Safety Lifecycle approach. The main benefit of applying the standard is that it provides a defined approach to determining system safety risk and reliability. The danger is that if it applied with excessive zeal it will add unnecessary cost.

Gordon Farquharson then spoke on Defining and Testing Room and Device Air Tightness. Leaktightness in a containment facility is important for keeping a biohazard in in the event of HVAC pressurisation failure, keeping a gaseous bio-decontamination agent in so as to maintain its efficacy and also keeping it in to avoid a chemical hazard outside the contained space as the ventilation might be turned off for that part of the process. Rooms are most often tested by the pressure hold method and microbiological safety cabinets by the pressure decay method. There are a number of international standards that give guidance and methods for testing leaktightness but, in Gordon's opinion the clearest to use is AS/NZ 2243.3-2010: Safety in laboratories – Microbiological safety and containment. This defines leakage by means of a leakage coefficient β (m^3/PA.sec), which is normally taken at 200 Pa, and also gives guidance values for particular situations. Gordon's talk went on to describe the options for construction and the importance of the specification and detail of components such as service penetrations, windows and doors. It is important not to overlook the reason for low leakage specifications for containment rooms. This is that fumigants and hazardous agents have to be contained when the ventilation is off or failed.

The next speaker, on the subject of safe work with biological agents, was Paul Logan, Head of Policy, Hazardous Installations Division, Health and Safety Executive (HSE), UK. We were privileged to hear of the future plans for the regulation in bio-safety in the UK in the light of the new coalition government's overall approach to regulation of business activities and, in particular, its spending review. The present set-up is fragmented, with the HSE being responsible for human pathogens and GMOs, and DEFRA (Department for Environment, Food and Rural Affairs) for animal pathogens. There is also overlap, so that for example zoonooses, which are of course both

human and animal pathogens, fall under both the HSE and DEFRA. The aim is to have an integrated regulatory position in the UK, to be set out in HSE Biological Agents and Genetically Modified Organisms (Contained Use) Regulations 2011, which will probably be published around April 2012. HSE will be expected to recover costs and they will do this by charging for inspections. Inspectors will not revisit if standards are known to be good thus penalising the less well managed sites who will suffer a greater number of chargeable visits! This is similar to 'the polluter pays' philosophy. In line with the new integrated approach, the new 'Approved List 2012' will, for the first time, include animal pathogens. Finally, it was very refreshing to hear a regulator express the view that prescriptive regulation squashes innovation!

Sustainability and containment – energy saving strategies and opportunities was the next subject and the speaker was again Gordon Farquharson. In the first part of his talk he described EN 16001, the energy management system standard which is another plan-do-check-act standard compatible with ISO 9001 etc. The BSI Cleanrooms Committee is currently drafting a code of practice style standard – BS 8568 – specific to cleanrooms, to support EN 16001. When this is complete, the committee may well move on to producing an equivalent document for containment facilities. Gordon started the next part of his talk by explaining how different nations generate different levels of CO_2 per kWh of power depending on the mix of coal, gas, nuclear and renewables. For example in Australia the accepted figure is 2.3 kg CO_2 per kWh due to most of the power coming from coal, whereas in France, the figure is 0.12 kg CO_2 per kWh, due to most of it coming from nuclear. In the UK, with its mix of generation methods, the figure is 0.54 kg CO_2 per kWh. As it is said that 50-80% of site energy is used for HVAC (heating, ventilation and air conditioning) this is a fruitful area to attack, and there are many opportunities – heat recovery from exhaust air, air volume set-back, correct selection of chiller type, high efficiency fan motors, high performance fan designs (and fans correctly sized so they run at their highest efficiency), lower pressure drop filters, AHUs (air handling units) and ducting etc. etc. Many HVAC engineers undersize AHUs and fans in order to save initial capital cost. This is likely to increase energy and maintenance costs, as well as noise, and is unlikely to give the optimum life cycle cost.

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The first day ended with a talk entitled 'Risk Assessment and Risk Management of Biosafety and was given by Uwe Müller-Doblies of BBSCR (Biotechnology and Biological Sciences Research Council) at Pirbright, UK, followed by a workshop exercise led by Uwe. Uwe started by defining Biorisk as the product of severity and probability of an adverse effect or damage arising from a biological hazard. This can be human injury, environmental release of an animal pathogen or an introduction of an alien species. He went on to distinguish between pathogen inherent hazards and protocol inherent hazards and to illustrate environmental and human health hazard groups and other risk factors with a series of explanatory graphics. This led to a discussion on several approaches to risk assessment ('assessing the credible failure paths to the top adverse consequences') including Uwe's favourite – Layer of Protection Analysis – and risk management, where he showed the 'bow-tie' risk management diagram. Here all threats are listed on one side, converging on the hazard release via threat control measures, then diverging again, via recovery/mitigation measures, into consequences. For a facility handling high consequence animal pathogens, an aspirational target of one consequential release in 500 years was suggested. There are many tools available, and CWA 15793, described earlier in the day by Steve Copping, fitted in well as a management system standard, albeit with a suspicion voiced by Uwe that it might mean different things to different people. The workshop exercise, set by Uwe, was to list and prioritise the five most important parameters that needed to be controlled for (1) human errors, (2) component failures, (3) services failures, (4) design failures and (5) procedural failures. This was a good way to end the day by applying some of the concepts we had learnt and led to lively discussions in the groups.

The second day started with an overview of issues facing the bio-safety professional by Heather Sheeley, Biosafety Programme Lead at HPA. Heather gave the WHO definitions of bio-safety:

Laboratory bio-safety describes the containment principles, technologies and practices that are implemented to prevent the unintended exposure to pathogens and toxins, or their unintended release.

Laboratory bio-security describes the protection, control and accountability for valuable biological materials in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release.

People are the hardest element to control. Heather encouraged a combination of support, understanding and engagement, and ethos, as well as 'design to encourage safe behaviour'. Here she gave the example of a change area that had been designed so that everyone entering the containment laboratory had to progress past a sequence of positions, each position having the items needed and clear pictorial instructions, so that it was impossible to don the laboratory garments in the wrong order. Regulation and governance is another issue. She welcomed the Single Regulatory Framework but was concerned about what might be found in the detail. She asked whether all regulatory documentation requirements added value, citing the example of having to report on the goal to reduce deaths by 10% when there have been no serious incidents in laboratories for many years, whereas the deaths from disease in the community, which the laboratories are fighting, are dire! Yet another issue is the public and regulatory perception and understanding of the science and of the risks. This is too much influenced by the

media who like to dramatise everything. Regarding concerns of terrorism there is a conflict between the importance of sharing the science and ensuring security. In America, psychometric testing is used to assess employees. Heather expanded on her slides, for example when sending materials for recycling, it isn't sufficient just to surface decontaminate containers (e.g. bottles) but the contents should be decontaminated as well. Control systems may be simple or complex, but simple is favoured from the health and safety point of view. The responsibility for bio-safety should be independent of line control. And in the design of facilities, don't inhibit what you might want to do in the future! Heather finished by telling us about the bio-safety associations that exist or are being formed around the world, our own being EBSA, the European Biosafety Association. The UK Institute of Safety in Technology and Research also has a high proportion of biosafety officers as members.

James Drinkwater, Process and Compliance Director of Bioquell UK, spoke next. His talk covered the evolution of Hydrogen Peroxide (H_2O_2) Vapour decontamination and whether it can replace formaldehyde decontamination as the benchmark process in bio-safety and bio-security applications. James made many claims for the efficacy of the H_2O_2 process and told us his company has referenced all peer-reviewed papers on the subject. He made the important point that cycle times were critical and told us that H_2O_2 is a 'lazy' gas by comparison with formaldehyde, needing kinetic energy to deliver it to the extremities of the space to be decontaminated. Apart from that, in a comparison with other decontamination methods, including foggers, atomisers, peracetic acid and chlorine dioxide, as well as of course formaldehyde, James showed us that H_2O_2 comes out well.

The two talks that followed were by Mark Bryan of HDR International and Andrew Watson of Wilkore Construction in Australia. Mark ranged from procurement strategy, to penetration details, to leak test methods, with leakage expressed in m3/m2.h, i.e. volume of leak, per square meter of surface (ceiling, walls and (possibly) floor). Andrew set the scene for his talk by describing biocontainment issues in Australia and telling us that AS NZS 2243.3:2010 specifies a value for the leakage coefficient β for high containment laboratories that gives a leakage rate, irrespective of room size, of 2 litres per second compared with 20 litres per second in the 2002 issue! Andrew's preferred construction method is the panel system and he listed the reasons. His talk also covered penetrations, other design details, QA documentation, installation and testing.

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Gordon Farquharson then gave a presentation on HEPA filters in safety applications with clear explanations of how HEPA filters work, MPPS (most penetrating particle size) and the difference between the manufacturers filter efficiency test and the installed filter penetration test. Some standards specify limits on overall penetration and others on local penetration (by scan testing) which is much more stringent. One issue with HEPA filters is the practicality of scan testing filters in every configuration, especially if they are close together in series. Gordon questioned whether bag-out systems are really necessary for bio-safety applications as they anyway need to be bio-decontaminated first. Bio-decontamination with formaldehyde and hydrogen peroxide vapour was discussed with the importance of the fumigant diffusing through the filter being a critical issue. The talk concluded with a very useful 'route map' for the specification of HEPA filters.

So far most of the talks had concerned containment, but Paul Barenton from Groupe Actini gave a most interesting presentation on biowaste treatment. This was in the form of a 'route map'. The treatment techniques available are heat and chemical, chemical being mainly for small scale applications. Heat treatment can be batch or continuous and Paul described how continuous systems can be single pass or can incorporate energy recovery and how the tubing itself can be used as the resistive conductor to generate the heat. Some calculations were shown showing the payback with different systems.

The final talk was given by Anton de Paiva who has recently been promoted from Biological Safety Officer at Imperial College to Deputy Safety Officer. This is quite a responsibility as there are 49 CL3 laboratories and 275 workers on a number of different sites. Anton started by relating how an incident in 1997 had been misrepresented totally by the press with headlines such as 'College workers exposed to death risk'! He gave several memorable examples of projects going wrong. A common thread was that the right people, namely the biological safety officer (and the end user) were not involved at the right time. Facilities were over designed and too complex, designed without risk assessments or built by the wrong people. If projects overran on costs, savings were made in the wrong areas. Anton's 'top tips' (for biosafety officers) for achieving an easy life were to muscle in on the design team, project management, commissioning, to accept only quality work, to be pragmatic where appropriate, and to be dogmatic where appropriate.

This was a good note on which to end the meeting. I would like to commend Management Forum for laying on such a comprehensive and well-run conference. The talks were excellent, the interactions were lively and there were plenty of opportunities to network and exchange views with colleagues. I hope the conference is repeated on a regular basis as the philosophy, the issues, the science and the regulatory framework are all changing very rapidly.

Please note that all the standards, guidelines and information on working groups mentioned in this report can be readily accessed via our associated website www.cleanairandcontainment.com.