Northern Biological Safety Officers Meeting

Minutes of the meeting held on 15th May 2009
University of Glasgow

1. Update on International Biorisk Management Standard

An outline of the previous framework for Biorisk management was given along with the recognition that an overarching document was needed to bring these together. The Biorisk management standard was intended to provide assurance to international community that there is a consistent approach to Biorisk management.

Development of the standard began in Oslo 2005 when all existing standards were reviewed. The International BioSafety Biosecurity Standard (CWA 15793) was published in Feb. 2008. Although there were 72 participants from 24 countries, it was noted that there was low participation from UK and University sector.

It was noted that those wishing to contribute to CEN Workshop Agreement and that comments may still do so. It was noted that the Workshop Agreement does not have to be implemented in all laboratories.

The Laboratory BioRisk Management Standard is voluntary and not a legal requirement, and aims to address both biosafety & biosecurity ('BioRisk'). Performance orientated and risk based, the standard is applicable to all organisations handling biological agents / toxins. The standard reflects the key principle of continual improvement that is associated with all quality management systems.

Future plans include a review of the standard in 2011 and development of guidance on implementation. There will also be the development of an accreditation / certification process.

The following points were raised in discussion:

- standard can be applied to a laboratory and not whole organisation
- Universities have not been engaged in the process - need to consider means of making funds available, possibly through USHA

2. Biosecurity update

A representative from the National Counter Terrorism Security Office (NaCTSO) reported that, as part of the review of the 'Schedule 5 list', the intention is to remove *Clostridium perfringens, Cryptococcus neoformans* and *Mycobacterium tuberculosis*. However, it was noted that as this still needs to be ratified by Ministers, it was likely to take two years before they are eventually removed.

An outline was given on each of the key elements of biosecurity, including physical, personnel, information, materials (keeping of/auditing) and transportation. The local Counter Terrorism Security Advisers (CTSAs)) are instructed on the fundamentals of biosecurity measures which include:

- achievable measures

- sustainable measures
- measures commensurate with level of risk
- measures which maintain scientific development

It was noted that new guidance for laboratories should be be released later this year. This will divide 'Schedule 5 organisms into 3 categories, with the levels of robust physical security measures needed dependant on the category of the organism..

It was reported that the Centre for the Protection of National Infrastructure (CPNI) provides protective security advice to businesses and organisations across the national infrastructure. Use of the website (www.cpni.gov.uk) was encouraged. Their broader guidance on personnel security should now be used instead of the previous guidance aimed at personnel security in laboratories issued by the Home Office)

'Project Revise', to be implemented shortly by local CTSAs and aimed at senior management within organisations will be a table top exercise with the focus on laboratories and their activities including the security of materials presenting a biosecurity risk.

The following points were raised in discussion:

- a further review of 'Schedule 5' organisms was needed
- frustration about having to declare holdings for chemicals
- NaCTSOs presentations should be targeted at a higher level within Universities (e.g. VC's) as well as those responsible for work activities (PI's / HoD)
- funding bodies should also be targeted to stipulate requirements- more likely to achieve better compliance

3. Update from HSE

An update on the Single Regulatory Framework (SRF) and an overview of the results of HSE commissioned research on room disinfection was given.

Single Regulatory Framework

A brief background to the SRF was given (as outlined in the minutes of the previous meeting in Manchester).

A phased approach (I – III) has been used to implement the recommendations; with the current state of play being nearly at Phase III, the implementation of SRF. The SRF will be implemented as the 'Biological Agents Contained Use' Regulations.

Risk assessment will represent a key element of the SRF. All biological agents will be assigned to 1 of 4 hazard groups; all laboratories to be assigned Containment Level 1 – 4; activities assessed and assigned to 1 of 4 activity classes (similar to current GM Contained Use Regulations). Class of activity will reflect consideration of organisms being used and what is actually being done with that organism.

It was noted that COSHH will no longer apply where deliberate work with biological agents (i.e. propagate or concentrate biological agent causing an increased level of

risk) takes place. However, COSHH will remain for activities involving incidental exposure to biological agents. COSHH will apply for work activity involving e.g. a clinical sample (which may contain a biological agent) provided not propagating / concentrating biological agents.

The intention is for lower risk Class 1 and 2 activities subject to a higher degree of self regulation. Class 3 and 4 activities will cover higher risk activities requiring more detailed regulatory intervention.

The concept of 'Connected Programmes' of work would be applied to non-GM work and derogation from certain containment requirements will still be allowed e.g. for some parasites.

The thorny subject of cost recovery was discussed. The HSE has to recover costs and is still considering a number of options including extending the fees to cover inspections and investigations.

A final draft of the guidance supporting the legislation (covering use of both human pathogens and specified animal pathogens) is expected to be completed in June 2009. A formal consultation exercise will follow before amending and publication. Full implementation is scheduled for April 2010 although most likely to be October 2010.

Whole Room Disinfection Study

A brief overview of the findings of the study to compare efficiency of a range of room fumigation methods, using formaldehyde as a control point of comparison was given. Given that the results had only just been received by HSE and had not yet been peer reviewed, it was agreed that the researchers should be invited to present their findings at the next meeting of the NBSOs.

4. Minutes of last meeting

The minutes of the previous meeting were accepted.

5. Steering Group Activities

- Notes that that reference to the International BioSafety Biosecurity Standard (CWA 15793) was made by the WHO regarding management of Inluenza
- Minutes of the last NBSO meeting will be added on the public site of ISTR as previously agreed
- Funding to cover travel costs of 1 speaker to be provided by ISTR
- Member of the steering group to be put forward as a co-opted member of ISTR EC as a means of maintaining the links with the regional groups

6. Next Meeting

- Next meeting scheduled to take place at Newcastle University on 4th December 2009. Main issue for discussion will be fumigation of containment laboratories.

7. Bio safety Professional Standards

An update on the ISTR accredited training scheme was given.

Level 1:

- Several organisations have expressed an interest as service providers
- Professional accreditation will be given
- Courses have started
- Assessors required

Level 2:

- Portfolio based; 6 mandatory elements; 2 optional
- Launch scheduled for September 2009
- Issue of 'Grandparent' rights still to be resolved

8. The Role of Biological Safety Advisers & Officers in the management of bio safety

The details of the results from the survey of the role of the BSO/BSA initiated in 2008 were presented A detailed report will be circulated to the group. The survey had highlighted that the role of the BSO / BSA is very variable and quite complex. Results were based on a total of 20 replies from 13 Universities, 3 Research Institutes and 1 Pharmaceutical company.

- A total of 12 different titles were used for Bio-Safety workers with variable commitments
- Most had primarily an advisory and training role. Some also had authority- both direct and indirect (e.g. Safety Committee). This could include approval of risk assessments, waste disposal contract management and approval of the acquisition of organisms. All will act 'in-extremis'.
- No correlation between titles and advisory / authority activities
- Some involved in activities beyond those associated with biological agents e.g. legionella control and pandemic flu contingency planning
- Most liaise with regulatory authorities such as HSE; licensing often left to PIs
- Wide variation in composition of Safety Office teams in terms of size and constitution
- The role of the BSA is quite elusive, that of the BSO is more clear cut.
- Biological Safety workers are all involved in classical bioscience and most in medicine. However, the survey indicated that few were involved in dentistry and especially veterinary science.
- All respondents involved in CL2 work activities, most with CL3 activities

Options for the future include correlating results before drawing the survey to a conclusion; adding comparison tables, conducting a more detailed survey.

The issue of training and job descriptions for Bio safety workers was discussed following the presentation. There are no formal requirements and many write there own job descriptions.

9. Feedback from regulatory visits

It was noted once again that SAPO inspectors were not able to apply the same level of discretion and flexibility than other regulatory inspectors. It is hoped that there will be a more consistent approach to inspections with the implementation of SRF.

No recent reports of 'Intervention Inspections' from HSE reported.

It was noted that there were plans for CTSA visits to become an annual event but it was reported that there is still a poor understanding of bio-safety issues amongst some CTSAs.

10. Current Issues

Pandemic flu

Most bio-safety advisers/officers are not directly involved in contingency plans for pandemic flu. It was felt that this is not necessarily a bio-safety issue but a continuity issue involving senior administrators.

Other issues for future discussion

Fumigation will be discussed at the next meeting. Other issues to consider for future discussion include: centrifuges, IVCs, work with parasites and revised guidance on use of Lentiviral vectors.