A need for an integrated management process for biorisks

Tony Della-Porta

Biosecurity and Biocontainment International Consultants (Bio2ic)
PO Box 531, Geelong VIC 3220
Email: Tony.della-porta@bio2ic.com

Biosafety has been a long-term issue in microbiology laboratories and has arisen out of the need to properly handle and prevent laboratory acquired infections. Yet, despite the adoption of a Standard for biosafety in Australia over 3 decades ago, such infections still occur.

Members of the Australian Society for Microbiology played a major role in the development of this Standard (*AS/NZS2243.3 – Safety in laboratories. Part 1. Microbiological aspects and containment facilities*). However, in most States and Territories, the Standard does not form part of occupational health and safety legislation and regulations, and hence laboratories do not feel compelled to abide with it. In contrast, the Australian Quarantine and Inspection Service (AQIS) and the Office of the Gene Technology Regulator (OGTR) regulations must be complied with by law. This conflict needs to be addressed urgently, as the organisms that are handled under these regulations also need to be handled as per the Standard. In addition, those laboratories which are not regulated by OGTR or AQIS, the vast majority, need to comply with AS/NZS2243.3.

A further complication is the need for regulators and certifiers to perform inspections and audits for compliance with their regulations or Standards. At present, both AQIS and OGTR perform compliance audits for their regulations; these are similar but differ in some aspects. The National Association of Testing Authorities (NATA) performs accreditation inspections of laboratories for their compliance with the quality assurance Standards ISO17025 and more recently ISO15189 (for medical laboratories): these are required by health and agriculture (veterinary) authorities. As you will see in the In Focus article on the revision of AS/NZS2243.3, AQIS, OGTR and the Standards Committee for AS/NZS2243.3 are working to get the Standards and the regulations to harmonise. This is a great move, but it doesn't lessen the burden of the inspections.

During the 1990s a new concern arose related to handling biological agents. This came about due to the failure of the Biological Weapons Convention, signed in the 1970s, to prevent Russia researching and manufacturing biological weapons through their Biopreparat Laboratories. Further, additional concern arose when an individual ordered a high risk biological agent from the American Type Culture Collection and it was discovered he was not associated with a laboratory; this lead to the development of the Select Agent Rule in the United States of America. This was further enhanced following the 9/11 incidents and the anthrax letters in the USA in October 2001. A new term called biosecurity was raised and significant controls and regulations were introduced to address this concern. Australia is in the process of addressing this, with a system that is much more sensitive to the requirements in order to not impair the ability of laboratories to operate and collaborate. This will result in the control and regulation of Security Sensitive Biological Agents (SSBAs).

There will therefore be a new lot of inspections required for laboratories handling SSBAs; this arose out of the Council of Australian Governments (COAG) Review of Biological Agents as part of their review into hazardous materials. This will come into force in 2009, following the enactment of the *National Health Security Act: 2007.* Standards are in the process of being developed for the handling of Tier 1 and Tier 2 agents and for their transport within Australia. The Department of Health and Ageing will administer the registration of facilities that handle these agents and will perform the registration inspections. This adds another inspection/audit to the already onerous requirements placed upon laboratories.

Discussions held by the World Health Organization and international biosafety associations have come up with a new term, biorisk, which incorporates both biosafety and biosecurity as these two areas cannot be separated. The risk of a release of a SSBA from a facility is probably 95% through a biosafety breach,

such as staff acquiring an infection, and probably less than 5% by deliberate terrorist or overt actions. The recent breaches at the University of Texas A&M of the Select Agent Rule, as reported by the Government Accountability Office of the United States, shows that it is dangerous to separate these two issues. However, in Australia we are doing just that.

During 2007, 76 participants from 24 countries worked on the drafting of a *CEN Work Agreement for Biorisk Management.* CEN is the European Committee for Standardisation and many European and ISO Standards are used around the world. The Laboratory Biorisk Management Standard (CWA 15793) came into existence from this work in February 2008. It is expected that CWA 15793 will become an ISO Standard after 3 years as a CEN Work Agreement – copies of the document can be obtained through Standards Australia.

This Standard covers both biosafety and biosecurity in the one document, and introduces a management approach which is based on the Plan, Do, Check, Act (PDCA) principles found in most quality assurance standards. This provides a process to ensure that any breaches and incidents are clearly identified and acted upon. Further, this Standard allows the country's regulations, codes of practice, legislation and Standards to become part of the process of meeting and documenting this Standard. It is also possible for accreditation bodies, such as the NATA, to accredit against this Standard and to have an interpretation covering the adoption of AS/NZS2243.3, AQIS and OGTR regulations and the Standards related to SSBAs. Further, each of the key groups could have a member on the peer review group for the facility audit.

However, this will require all the key players to come to the table and agree that they are willing to work to a more efficient and, I believe, effective system. It would not only reduce the number of audits, but provide a clear management system within the facility that must demonstrate effective implementation of the requirements and a process of checking compliance.

I hope that we can all encourage the development of a more effective system for the management of biorisks in our facilities and a more efficient and cost effective way of monitoring compliance with the relevant requirements. Also consider getting your laboratory accredited under CWA 15793 and you will know that you have an effective system to manage biorisks.