Implementation of a Biosafety Facility Internal Certification Program at an Australian University

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Abstract

Objective: To describe the internal process used to certify facilities where biohazardous materials are handled, to improve oversight and risk management of biological research that is not externally regulated.

Method: The process has been adapted to intrinsically motivate facility personnel to determine area–specific biosafety measures

Results: Facilities certified to date and the types of issues identified. **Discussion:** What worked well, the challenges faced and lessons learnt.

Outcome: Improved oversight of hazardous biological research as well as an improved safety culture within facilities ensuring a greater likelihood of behavioral compliance with the biosafety measures implemented.

Introduction

The University of Melbourne has a documented *Biosafety Management Strategy* focused on best practice in institutional biosafety oversight. The strategy's aim is to implement effective biosafety measures to minimise risk associated with biological research.

In 2012, a university-wide *Biological Risk Survey* was performed to update centrally held records of biological materials handled and stored. Findings from this survey were finalized in 2013. They indicated that multiple research groups handle biohazardous agents and materials which are not directly regulated by external legislation.

The University launched a *Biosafety Program* in late 2013 comprising several measures for the safe handling and containment of the biohazards identified in the Survey.
It included three University policies:

Facility Internal Certification - **Biosafety laboratories and other facilities not already monitored for compliance with legislated biosafety criteria are required to be internally certified and monitored by the Institutional Biosafety Committee (IBC). The process and approach used to implement this policy is the focus of this poster.**

Infectious Agent Reporting - An inventory of hazardous infectious agents (RG2 and above) must be kept and newly acquired agents reported to the biosafety office.

Infectious Agent Project Approval - High-risk research or work involving Risk Group (RG) 3 or 4 agents must first have IBC approval.

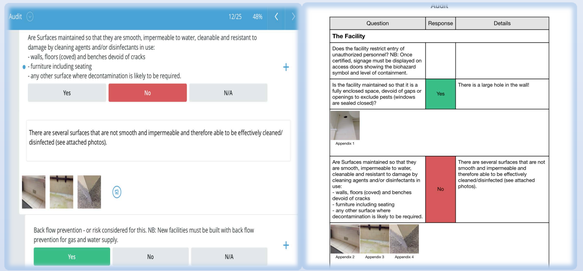


Fig 1. Example of an 'iAuditor' biosafety facility checklist and report

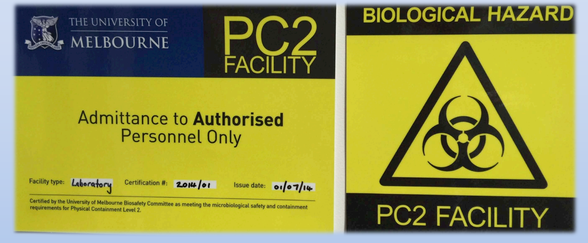


Fig 2. University of Melbourne certification signage NB: PC2~BSL2

Method

1. **Communicate:** Information seminars used to raise awareness of the program and provide an overview of the *Biological Risk Survey* findings.

2. **Identify:**
- Phase 1 = 'Self-identification' by research groups following the information seminars.
- Phase 2 = Remaining groups identified based on Survey information and infectious agent reporting.

3. **Inform:**
- Preliminary inspections of facilities determine compliance against IBC approved requirements.*
- A gap analysis report (generated using an iPad and iAuditor 'App') is provided; report describes requirements to be addressed in order to achieve internal certification. *Fig 1.*

4. **Support:**
- Facility personnel determine area–specific solutions to address the gaps identified.
- Support provided by the BSO includes the provision of guidance documents, links to resources, document review and referral to contacts such as EHS, property and facility management personnel.

5. **Review:** Internal certification is applied for using application form available on University website. Approval is provided by the IBC when the facility has met requirements and has biosafety measures appropriate for the research conducted in place.

6. **Certify:** An IBC letter and University signage (*Fig 2.)* is provided to the facility contact person. The letter specifies the conditions (including annual monitoring) associated with ongoing facility approval.

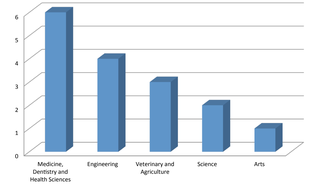
Results

- 16 facilities have been inspected; 10 have achieved internal certification to date – eight labs, one animal and one arthropod facility.
- Time to certification has varied from one week to 12 months; with an average of five months - Facilities with longer certification times required physical maintenance OR area-specific documentation.
- The number of facilities requiring certification was found to be significantly less than predicted based on Survey findings - Multiple research groups shared a facility or worked in one certified for rDNA work

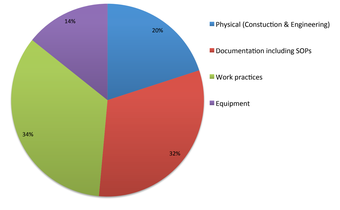
Discussion Table

What worked	Challenges	Lessons Learnt
Using seminars to promote the program	Explaining program focus is on non rDNA biohazards	Be visible, available and offer guidance (rather than policing research)
Use of Biological Risk Survey and ongoing infectious agent reporting to identify facilities requiring certification	Program halted by major university restructure (due to effect on network of key contacts)	Program implementation greatly aided by network of departmental contacts
Highlighting area-specific hazards associated with work performed	Not overwhelming personnel with information or control measures	Inspections are an opportunity to educate, get buy-in and empower others to do biosafety
Communicating suggested improvements to SOPs in person	Providing guidance to those writing SOPs and assessing biological risk due to time commitment	Use of a biosafety template provides consistency and saves time
The use of inspection tools (ipads & customizable iAuditor 'App') to enable efficient communication of gaps	Finding a balance between intrinsic motivation and providing sufficient support	Step back after providing information - be flexible and outcome focused
Having a team approach	Working with different personality types or unmotivated people	Provide support face to face when possible - be kind

Number of Facilities Inspected per Faculty



Types of Issues Identified



Conclusion

The approach used has achieved compliant and safe facilities, whilst building biosafety understanding and capability within these areas. Though a protracted process, it has built trust between personnel and the University's Biosafety Officers. A team approach to continuous improvement of biosafety has ultimately improved the culture of safety.

* Requirements are based on the Australian-New Zealand laboratory safety standard AS/NZS 2243.3:2010 Microbiological safety and containment. This describes current knowledge in microbiological safe practice. It outlines the physical, work practice and administrative controls required for Physical Containment Levels 1-4 (PC1-4) equivalent to Biosafety Levels 1-4 (BSL1-4).

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