

CHARLES STURT
U N I V E R S I T Y



BIOSAFETY MANUAL



This Manual was compiled by members of the University Biosafety Committee. Charles Sturt University wishes to thank CSIRO, the Australian National University and other university collaborators for their contributions towards this document

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1.1 Preface

This Manual is intended to provide guidance to staff and students at Charles Sturt University handling, or exposed to, potentially biohazardous material during their learning, teaching and research. It contains policies, procedures and guidelines which are intended to *minimise the risk* of infection or injury arising from contact with biohazardous material. It also provides some useful general information in the Appendices. It is *not intended* to be a comprehensive manual on all aspects of the safe handling of biological material.

All Schools and Centres at the University working with biohazardous material are expected to develop their own Standard Operating Procedures (SOP) which are consistent with the requirements outlined in the policies, guidelines and procedures within this Manual. Once developed, these School/Facility SOP should be referred to the Biosafety Committee for consideration, to ensure consistency across the University.

Clause 4 of the University *Code of Conduct for Research* requires that all researchers ensure the safety and well-being of all humans involved in research. To effect this principle, all researchers must obtain the approval of the Biosafety Committee for research proposals involving the use of genetic manipulation techniques or virulent or toxic organisms or substances. With the introduction of the Commonwealth *Gene Technology Act (2000)* and *Gene Technology Regulations (2001)*, any activity or experimentation (including undergraduate class practicals) involving *Genetically Modified Organisms (GMOs)* – as defined in the Act, Regulations and other publications produced by the Office of the Gene Technology Regulator – must be reported to the Committee. Certain categories of experimentation, discussed elsewhere in this Manual, must be reported to the Regulator; other categories (licensed dealings) require the approval of the Regulator. An Annual Report, which includes a listing of all GMO work (known as ‘dealings’) conducted by the University, must be submitted to the Regulator each year.

As a final note, it cannot be over-emphasised that no research or teaching with potentially biohazardous material should be undertaken until a thorough Risk Assessment has been completed (which incorporates procedures for dealing with a range of maximum conceivable incidents/accidents) and approved by the relevant Head of School or Centre Director.

Comments and criticisms regarding the content and scope of this Manual are welcome and should be forwarded to the Executive Officer, Biosafety Committee, Office of Academic Governance, Bathurst Campus.

1.2 Biosafety Committee members

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Ms Natalie Allison	Laboratory Manager, Sutherland Laboratories.....	69332350
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Mrs Lyn Matthews	Biological Safety Officer.....	69332353
Mr Peter Maxwell.....	Manager, Environment, Health & Safety	69512713
Ms Lesley Stoneman.....	Executive Officer.....	63384091
Mr Charles Svenson.....	Manager, University Laboratories.....	63657544

1.3 Web addresses

Organisations

Biosafety Committee Home Page	http://www.csu.edu.au/acad_sec/committees/biosafety/
Australian Quarantine and Inspection Service	http://www.affa.gov.au/
National Health and Medical Research Council	http://www.nhmrc.gov.au/
Office of the Gene Technology Regulator	http://www.ogtr.gov.au

Forms

Accident/Incident Report Form	http://www.csu.edu.au/division/healsafe/textdocs/forms/AcclncReport.xls
Biological Accident/Incident Report (Appendix 4)	http://www.csu.edu.au/acad_sec/committees/forms/bsc1.doc
Clearance for maintenance work within/ to a biological facility (Appendix 5)	http://www.csu.edu.au/acad_sec/committees/forms/bsc2.doc
Exempt Dealing Evaluation Report (Appendix 6)	
Exempt Dealing Evaluation Report (Undergraduate Classes) (Appendix 7)	

Standards

Australian Standards	http://online.standards.com.au/online/autologin.asp
AS/NZS 2243.1:1997 Safety in laboratories Part 1: General	
AS/NZS 2243.3:2002 Safety in laboratories Part 3: Microbiological aspects and containment facilities	
AS/NZS 2647:2000 Biological safety cabinets – Installation and use	
AS/NZS 2982.1:1997: Laboratory design and construction – General requirements	

Guidelines

Guidelines for Certification of Facilities/Physical Containment Requirements	http://www.ogtr.gov.au/pubform/certification.htm
Guidelines for the Safe Transport of GMOs	http://www.ogtr.gov.au/pdf/handbook/appendix5.pdf
Handbook on the Regulation of Gene Technology in Australia	http://www.ogtr.gov.au/pubform/handbook.htm
Material Safety Data Sheets for various risk group micro-organisms	http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/index.html#menu
Safety Manual for Researchers in Biotechnology Laboratories	http://www.istge.it/library/libri/safeman/istpdfeng.pdf

Other sites of interest

Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety/default.aspx
USOHS Biosafety in Microbiological and Biomedical Laboratories	http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm
International Centre for Genetic Engineering and Biotechnology	http://www.icgeb.org/~bsafesrv/

2.1 Staff vaccination/inoculation policy

Approved by Board of Governors on 11 April 1997
Version: 6 September 2004
Next Review: September 2006
Administered: Corporate Governance

Statutory requirements

"An employer must ensure the health, safety and welfare at work of all the employees of the employer."
SECTION 8 (1) OH&S Act 2000

Policy

General approach

Where a vaccination or a seroconversion test is required to protect staff when undertaking their normal duties, including overseas travel on University business to areas of proclaimed infectious risk for which a vaccination exists, then the cost centre that employs that staff member shall pay any costs associated with the required screening and vaccination. Vaccination for personal travel is the responsibility of the individual staff member.

Where there is a University requirement to provide a service, additional to the duties covered by that staff member's employment, such as the provision of first-aid services, then the Division of Human Resources shall meet all costs for the required vaccinations. Refer also to the University's "First-Aid Policy", for specific detail.

Where there are strategic or financial benefits to the University from undertaking a vaccination program, and that program has been approved, then the Division of Human Resources shall be funded for, and shall meet all costs associated with that program.

Notifiable infectious diseases

Notifiable infectious diseases are the responsibility of the NSW Public Health Units (PHUs) to administer and manage, due to the privacy and ethical requirements. The University is not empowered to fulfil these functions, other than the operation of a confidential 'notification of infectious diseases protocol' that is in existence at each campus. These protocols are used to liaise with PHUs and to assist in the management of PHU programs if requested. A program need is based on a PHU risk assessment for each notified case. Where a program is undertaken, the PHU will arrange for all screening, information sessions and vaccinations (if available) without charge to individuals.

Staff seeking screening or vaccinations outside of PHU programs, will be required to cover all incurred costs themselves. Managers are not to authorise any claims for such reimbursement. Staff who assess their personal safety beyond the assessed risk levels, can utilise their recreational or flexible leave balances, for the period of any perceived threat.

Record keeping

Record keeping for the purposes of screening and vaccination are the responsibility of individual staff members, using recommended personal record cards/ booklets, such as the 'Adult Vaccination Record Card' available free of charge from the Bathurst or Wagga Wagga Medical Centres. It is the responsibility of staff to keep their individual records up-to-date, and to provide this record to managers upon request and prior to approval for business travel to areas of infectious risk, or to organisations requiring proof of vaccination status, such as hospitals.

Rights and obligations

Whilst individuals reserve the right not to partake in screening or vaccinations, the University is obliged not to place staff into areas or tasks where the risk level or outcome is unacceptable, especially where no preventative vaccination has been undertaken. It should be noted that a record of screening/ vaccinations against NSW Health Department listed infectious diseases is a prerequisite for approval to access their sites.

2.2 Policy for the use of human biological specimens in undergraduate and research laboratories

Approved by Board of Governors on 11 April 1997; amendments approved by the University Council on 30 May (CNL 02/74) and 26 November 2002 (CNL 02/173)

Version: 31 October 2002

Next Review: October 2004

Administered: Centre for Research & Graduate Training

Statutory requirements

Occupational Health and Safety Act 2000 Sections 8(1) and (2).

The following standards will be followed to meet the University's obligations under the Occupational Health and Safety Act:

Australian Standard AS 2243.1 – 1997 Safety in Laboratories Part 1: General; and

Australian Standard AS 2243.3 – 2002 Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities.

Preamble

In some laboratory practical classes, exercises using blood have been devised where the blood samples used are obtained from volunteer staff, students and patients by venepuncture or a finger prick. Other body fluids or tissue (e.g. urine, saliva and cheek cells) may also be utilised.

Some research projects also require the collection and handling of blood and other materials of human origin.

Policy

All samples used by students will be either from screened donors (i.e. showing negative serology/virology for syphilis, Hepatitis B and C, and HIV) or provided by students who will be testing their own body samples themselves.

Teaching and research activities that cannot meet their objectives through the use of the types of sample outlined above *must* obtain approval for an exemption to this policy ¹. The application for an exemption should be made in writing, be addressed to the University Biosafety Committee and should include a detailed risk management protocol.

No body samples from unscreened donors (with the exception of the samples provided by the students for their self-testing) shall be used unless approval for that specific activity has been provided, in writing, by the Biosafety Committee.

All Human Biological specimens should be regarded as infectious at all times.

¹ See *Protocol for Granting an Exemption to the Requirements of the Human Biological Specimens Policy* at Appendix 10, *Biosafety Manual*.

Procedures

Standard (Universal) precautions should be adhered to at all times when handling material of human origin (blood, body fluids and tissue). (See *Infection Control in Health Care Settings: Guidelines for the Prevention of Transmission of Infectious Diseases*, National Health and Medical Research Council).

Procedures should be adopted that minimise the chance of accident by needles and other sharp implements which cause injury.

Avoid contact with material of human origin and minimise risk by wearing disposable gloves, protective gowns and protective eye wear if appropriate.

At the conclusion of all procedures, wash down bench tops and other surfaces with an appropriate disinfectant, for example, a strong solution of sodium hypochlorite (approximately 0.5% available chlorine), followed by 70% (w/w) alcohol (80% v/v), discard gloves into contaminated waste bag, place protective clothing in laundry bag and wash hands thoroughly with soap and water.

In the event of an accident involving Human Biological Specimens, report it immediately to your supervisor or staff member in charge of the area or class where the accident occurs, and ensure that your supervisor follows up this action within 24 hours with the submission of a Biological Accident/Incident Report, using **form BSC1** (available from the Web) to the Biosafety Committee.

Any accident involving injury or contamination to staff, students or visitors shall *also* be reported to the Human Resources Office using the *Charles Sturt University Accident/Incident Report Form* available from the Web (**NB**: This form is a separate one to BSC 1).

See also *Procedures for Dealing With Biological Accidents/Incidents* in the Biosafety Manual 4.1.

Sharps protocol

1. Needles and syringes are to be discarded only into approved containers.
2. Never attempt to replace the cap on a needle after use as this may lead to a 'finger-stick' injury.

Injuries

For injuries involving Human Biological Specimens, proceed to the Campus Medical Centre, or nearest hospital emergency department. This should be done without delay so the incident can be assessed and treatment offered within 24 hours if warranted.



As indicated at *Procedures* above, ensure that you submit a *Biological Accident/Incident Report* (form BSC 1) to the Biosafety Committee within this same time period. Detailed guidelines are provided within the *Procedures for Dealing With Biological Accidents/Incidents* in the Biosafety Manual).

Spills

1. If any body fluid is spilled, it should be cleaned up immediately with, for example, a strong solution of sodium hypochlorite (approximately 0.5% available chlorine), followed by 70% (w/w) alcohol (80% v/v).
2. Laboratory coats contaminated with body fluid must be decontaminated; for example, by placing in a chlorine bath for 30 minutes, prior to normal washing.
3. Material used to clean up the spill must be appropriately decontaminated prior to disposal; for example, by autoclaving or chemical sterilisation (NOTE: *Do not* autoclave materials soaked with hypochlorite solution due to the risk of toxic gas being produced).

3.1 Guidelines for minimising the risk of HIV/AIDS and hepatitis infection

Originally approved in 1994 (Deputy Vice-Chancellor); amendments approved by Board of Governors in July 1994 & by Pro-Vice-Chancellor (Research & Graduate Training) on 5 June, 4 September & 2 December 2002
Version: 1 November 2002
Next Review: November 2004
Administered: Centre for Research & Graduate Training

Principles to minimise the risk of infection

Staff, students and visitors shall be classified into high, medium, and low risk categories.

Workplace Locations throughout CSU shall be classified similarly according to the risk to users.

Awareness shall be developed among all staff, students and visitors commensurate with their level and type of risk.

Appropriate steps shall be taken with each risk category to minimise their risk of infection.

Administrative structures

The Biosafety Committee shall have expert members only, nominated by the Pro-Vice-Chancellor (Research and Graduate Training).

The powers and responsibility of the Biosafety Committee in administering these guidelines, as approved by the Board of Governors on the 17 August 1995, are:

- a. to classify staff, students or visitors into high, medium or low risk categories;
- b. to classify locations in CSU into high, medium or low infection risk categories;
- c. to assist in the development and delivery of educational programs to generate appropriate levels of awareness amongst all staff, students and visitors at CSU;
- d. to develop and promulgate policies which minimise the risk to staff, students and visitors of CSU;
- e. to recommend to the Pro-Vice-Chancellor (Research and Graduate Training) mechanisms to minimise the risk to all staff, students and visitors of CSU; and
- f. to monitor the implementation of relevant policies and procedures as determined by the University and outlined in these guidelines. These policies include the HIV/AIDS and Hepatitis Policy, Policy for the Use of Human Biological Specimens in Undergraduate and Research Laboratories and the Staff Vaccination/ Inoculation Policy.

Guidelines to minimise the infective risk to staff

Staff (academic, non-academic, full-time, part-time, casual or contract) shall be classified into high, medium or low risk, according to their risk of infection in carrying out their normal duties, as set out in the job description. Such classification will be performed by the Biosafety Committee and recommended to the Pro-Vice-Chancellor (Research and Graduate Training) for endorsement. Officially designated first-aid officers shall be automatically placed in the high risk category.

Workplace locations within CSU shall be classified into high, medium or low infective risk to their occupants. Under normal circumstances, only staff members classified as high risk will be required to work in a high risk location. **High risk locations must be clearly indicated by signs on all entrances to facilities indicated in the Biosafety Committee's 'Workplace Location Risk Classifications' originally approved 6 March 1997.**

Staff classified as high risk:

- a. are entitled to appropriate protective clothing, and appropriate laundering of soiled and protective clothing;
- b. shall be offered free vaccination against Hepatitis A or B or both, according to the vaccination requirement indicated in the Biosafety Committee's 'Risk Classifications for Staff, Students and Visitors' approved 22 May 1997, and the University's 'Staff Vaccination/Inoculation' policy;

- c. shall be given detailed instructions on the procedures required to minimise their risk of infection;

Staff classified as medium risk:

- a. shall be offered free vaccination against Hepatitis A or B or both, according to the vaccination requirement indicated in the Biosafety Committee's 'Risk Classifications for Staff, Students and Visitors' approved 22 May 1997, and the University's 'Staff Vaccination/Inoculation' policy;
- b. shall be given appropriate instruction in the procedures required to minimise their risk of infection.

Staff classified as low risk shall be given instruction aimed to raise their awareness of potential infective agents in their work environment and in basic procedures to minimise their risk of infection.

Guidelines to Minimise the risk of infection to students and visitors

Only students in courses where there is a professional requirement for students to be trained in a potentially infectious environment will be placed in the high risk category. Currently, students enrolled in Medical Laboratory Science, Nursing, Medical and Applied Biotechnology, Physiotherapy, Occupational Therapy, Nutrition and Dietetics, Speech Pathology, Podiatry, Clinical Practice (Paramedic), Nuclear Medicine Technology, Human Movement, Social Work, Social Welfare and Policing courses are classified in the high risk category and Wine Science students in the medium risk category. Students entering these courses shall be informed of the level of risk and the steps that they should take to minimise their risk of infection.

Only students in the high risk category are permitted to perform laboratory experiments involving material of human origin. Such experiments can only be performed:

- a. in designated high risk laboratories;
- b. after satisfactory completion of an intensive course of instruction on the infective risks and procedures to be followed to minimise this risk;
- c. following the procedures outlined in the University's Policy for the Use of Human Biological Specimens in Undergraduate and Research Laboratories.

Students classified in the high risk category shall be offered vaccination against Hepatitis A or Hepatitis B, or both, at cost (i.e. at the cost of the vaccine only) through the Charles Sturt University Medical Centres, where they exist.

Students participating in clinical practice in NSW health care facilities (coming under the auspices of the NSW Health Department) shall follow the screening and immunisation requirements outlined in the NSW Health Department Circular Number 2002/97: "*Occupational Screening and Vaccination Against Infectious Diseases*" (issued 18 October 2002).

Students participating in clinical practice in facilities **other** than those overseen by the NSW Health Department should follow the infection control procedures set down by their host institution and/or relevant State Health Department.

3.2 Guidelines for staff Mantoux screening

Originally approved by the Vice-Chancellor in May, 1997; amendments approved by the Pro-Vice-Chancellor (Research & Graduate Training) on 2 April 2002

Version: 13 March 2002

Next Review: March 2004

Administered: Centre for Research & Graduate Training

Statutory requirements

“An employer must ensure the health, safety and welfare at work of all the employees of the employer.”
SECTION 8 (1) OH&S Act 2000

Guidelines for staff Mantoux screening

Mantoux screening should be made available to staff on all campuses servicing courses where students are trained in a potentially infectious environment (including but not limited to nursing, medical laboratory science, occupational therapy, radiography, medical and applied biotechnology, physiotherapy, nutrition and dietetics, speech pathology, podiatry and clinical practice [paramedic]).

Heads of School providing staff in the above courses should be permitted to offer to arrange for screening of those of their staff they consider to be in the “high risk” category.

3.3 Guidelines for exposure to bats

Originally approved by the Vice-Chancellor on 12 June 1997
Version: 13 February 2002
Next Review: February 2004
Administered: Centre for Research & Graduate Training

Statutory requirements

“An employer must ensure the health, safety and welfare at work of all the employees of the employer.”
SECTION 8 (1) OH&S Act 2000

“An employer must ensure that persons (other than the employees of the employer) are not exposed to risks to their health or safety arising from the conduct of the employer’s undertaking while they are at the employer’s place of work.”
SECTION 8 (2) OH&S Act 2000

Guidelines for staff and students of the university who have an occupational or recreational exposure to bats

Background

A new *Lyssavirus* was identified during 1996 in two species of bat in Australia. The two species are the Black flying fox (*Pteropus alecto*) and the Little Red flying fox (*Pteropus scapulatus*). In November 1996, a woman in Queensland developed encephalitis, probably due to the virus, after being bitten and scratched by bats.

The genus *Lyssavirus* falls within the family Rhabdoviridae. There are six genotypes recognised within the genus. These include the classic rabies virus, Lagos bat virus, Mokola virus, Duvenhage virus and the two European bat *Lyssaviruses*. These viruses have not previously been reported to occur in Australia. The newly identified seventh *Lyssavirus* is closely related to, but distinct from, the classic rabies virus. In laboratory animals, rabies vaccine and rabies immunoglobulin are protective against this new *Lyssavirus*.

Non-rabies *Lyssaviruses* usually do not spread among terrestrial animals and human infections are rare. The newly identified *Lyssavirus* is currently only known to infect fruit bats (flying foxes) and humans. Insectivorous bats are known to carry other *Lyssaviruses* overseas and therefore cannot be discounted as a potential risk, at this stage.

Rabies virus and other *Lyssaviruses* are usually transmitted to humans via bites or scratches which provide direct access of the virus in saliva to exposed tissue and nerve endings. This means that most people would not be exposed to *Lyssavirus* through casual contact with bats.

As the bat *Lyssavirus* is closely related to classic rabies virus, infection may be prevented by rabies vaccine and rabies immunoglobulin. Recommendations for administering these are provided below. Further research is being conducted into the distribution and transmissibility of the virus. Recommendations may be updated as more information becomes available.

Recommendations

Pre-exposure vaccination

Pre-exposure vaccination should be recommended to those occupationally or recreationally exposed to bats, where there is a risk of being bitten or scratched, for example:

- Bat carers
- Veterinarians
- Veterinary laboratory staff
- Researchers
- Research laboratory staff
- Wildlife Officers (including local government officers)
- Managers of display or research colonies
- Members of indigenous communities who may catch bats for consumption, and

- Powerline workers who frequently remove bats from power lines.

Pre-exposure vaccination consists of three intramuscular doses of 1ml rabies vaccine given on days 0, 7 and 28. Doses should be given in the deltoid area, as rabies neutralising antibody titres may be reduced after administration in other sites. In children, administration into the anterolateral aspect of the thigh is also acceptable.

Persons bitten or scratched by bats

The wound should be scrubbed thoroughly as soon as possible with soap and water. Proper cleansing of the wound is the single most effective measure for reducing the transmission. Where possible, the bat should be kept for further investigation by the State Veterinary Laboratory.

Guidelines have been developed to aid the decision on whether to administer vaccine alone or combined with rabies immunoglobulin. Factors include the type of wound, how recent the exposure was and the behaviour of the bat. Please contact your public health authority who will provide advice on the appropriate course of action.

Contact such as patting bats or exposure to urine and faeces does **not** constitute an at risk exposure. Pre-exposure vaccination should be offered if the person has on-going contact with bats.

3.4 Risk classifications for staff, students and visitors

Originally approved by Biosafety Committee on 22 May 1997; amendments approved on 5 June & 27 November 2001, & 5 June, 4 September & 2 December 2002
(Pro-Vice-Chancellor [Research & Graduate Training])

Version: 7 November 2002

Next Review: November 2004

Administered: Centre for Research & Graduate Training

High risk workplace locations¹

Vaccination Requirements: Hepatitis A & B

- Laboratory workers, technical staff, teaching staff and students working in High Risk locations
- Cleaners working in laboratories
- Technical staff, teaching staff and students required to undertake clinical experience which exposes them to clients within the health system
- Teaching Staff who, during clinical liaison visits and/or clinical supervision of students, are exposed to clients within the health system
- First Aid Officers
- Medical Centre Staff
- Plumbers and Sewage treatment staff

Vaccination Requirements: Hepatitis B

- First Aid Officers

Medium risk workplace locations¹

Vaccination Requirements: Hepatitis A & B

- Laboratory workers, technical staff, teaching staff and students working in Medium Risk Locations
- Grounds staff required to clear drains and gutters
- Childcare Workers
- Cleaners other than laboratory cleaners

Vaccination Requirements: Hepatitis B

- Security Officers
- Medical Receptionist
- Housemaids
- Staff working with students in Workshop facilities
- Student Services counsellors
- Garbage collection Staff - other than laboratory areas

Low risk workplace locations¹

Persons in Low Risk Workplace Locations have no vaccination requirements.

1. See Section 3.5 Workplace Location Risk Classifications of the Biosafety Manual.

3.5 Workplace location risk classifications

Originally approved by Biosafety Committee on 6 March 1997; amendments approved on 13 March 2001 (BSC 01/13); 27 November 2001 (BSC 01/47) & by the Pro-Vice-Chancellor (Research & Graduate Training) on 5 June, 4 September & 2 December 2002.

Version: 7 November 2002

Next Review: November 2004

Administered: Centre for Research & Graduate Training

High risk workplace locations

- **Medical Centres on each Campus**

Wagga Wagga

- **David Morell Laboratories** (Building 10):
Rooms: 208, 211, 215, 224, 225, 228, 229, 230, 231, 232, 233, 251, 133, 243, 244, 245, 246 and 248 (Nursing Laboratory complex)
- **Environmental and Analytical Laboratories** (Building 269):
Rooms: 101, 103, 105, 106, 110, 111, 112 and main laboratory area
- **Nuclear Medicine** (Building 10): Room 135
- **Nutrition Clinic** (Building 3): Room 217

Bathurst

- **Science Laboratories** (Building S15): Rooms: 2.01, 2.04 (& Prep. Room)
- **Science Laboratories** (Building S21):
Rooms: 101 (Human Performance Laboratory), 107/108 (Prep Room), 109 (Autoclave Room), 110 (Prep Room) and 111 (General Teaching Laboratory);
- **School of Nursing and Health Science Laboratories** (Building S14):
Rooms 101, 102, 103 and 104;
- **School of Public Health Clinical Laboratory** (Building N10)

Albury-Wodonga

- **School of Community Health Anatomy Laboratory**
All rooms except the staff office
- **School of Community Health Physiology Laboratory**
All rooms except the staff office;

Medium risk workplace locations

- **Childcare Centres**

Thurgoona

- **School of Environmental & Information Sciences Ecology Laboratory** (Building 666)

Wagga Wagga

- **School of Wine and Food Sciences Wine Tasting Laboratory** (Building 404): Room 113

Low risk workplace locations

All other workplace locations not mentioned in high or medium risk categories.

4.1 Procedures for dealing with biological accidents/incidents

Originally approved by the Pro-Vice-Chancellor (Research & Graduate Training) on 30 August 2002

Version: 28 August 2002

Next Review: August 2004

Administered: Centre for Research & Graduate Training

Scope

The following procedures are applicable to all facilities at Charles Sturt University conducting experiments with potentially biohazardous material. **Prior to any work being commenced with such material, an appropriate Risk Assessment shall be undertaken, which will include Standard Operating Procedures for all activities to be conducted, and incorporate *project-specific* procedures for dealing with maximum conceivable accidents/incidents.**

Definitions

<i>Accident</i>	For the purposes of these procedures, an <i>accident</i> is defined as any uncontrolled or unintentional release of a biological agent, either within a contained facility or into the environment, and/or contamination of personnel, which <i>seems likely to result in injury or illness</i> to the personnel so exposed (i.e., more serious than an <i>incident</i>).
<i>Incident</i>	An <i>incident</i> is defined in these procedures as an uncontrolled or unintentional release of a biological agent which, although not actually causing injury/harm to personnel or to the environment, <i>had the potential to do so</i> (i.e., 'a near miss').
<i>Biohazardous Material</i>	<i>Biohazardous Material</i> is defined as any agent of biological origin which has the capacity to produce deleterious effects on humans and/or the environment. The <i>degree</i> of the hazard (and, consequently, the response to any accidental spillage) will depend on the <i>Risk Group, form</i> and <i>volume</i> of the material involved.
<i>Risk Group</i>	Micro-organisms are classified according to their degree of risk to individuals, the community or the environment. The <i>Risk Groups</i> for some classes of micro-organisms are outlined in the Australian Standard AS 2243.3 (2002): " <i>Safety in Laboratories – Microbiological Aspects and Containment Facilities</i> ". These University procedures are particularly relevant when dealing with micro-organisms of Risk Group 2 and above .
<i>Risk Levels of Spillage</i>	The risk level of the particular spillage is determined by the nature of the biological material involved and the level of containment.
<i>Low Risk Spillage</i>	A <i>Low Risk Spillage</i> involves a biohazardous material release which is contained within a biological safety cabinet or within a facility which is appropriate for the Risk Group of the micro-organism involved.
<i>High Risk Spillage</i>	A <i>High Risk Spillage</i> involves two possible scenarios: a release of a biohazardous material outside of the appropriate level of containment; or a release of a biohazardous material which creates a risk to human health.
<i>Genetically Modified Organism (GMO)</i>	The term <i>GMO</i> is as defined in the Commonwealth Gene Technology Act 2000 and the Gene Technology Regulations 2001 (available via the Biosafety Committee Home Page). The term includes tissue culture cell lines, micro-organisms, viruses and any other biological entity which has undergone genetic manipulation, apart from those classes of organism declared by the Regulations <i>not</i> to be GMOs.

Reporting of accidents and incidents

In the event of an *accident* (as defined above), priority must be given to the care of the injured. After due consideration of the risk level of the biohazardous material involved, first aid should be applied by trained personnel.

Every accident or incident involving biohazardous material shall be reported immediately to the appropriate supervisor, and followed up within 24 hours by submission of a Biological Accident/Incident Report (using form BSC 1 – see Appendix 4 or available from the Web) to the Biosafety Committee.

If the material involves GMOs, the Biosafety Committee shall then forward a copy of the report to the Office of the Gene Technology Regulator (OGTR). **(NOTE: Where there is a risk to human health or the environment, the accident must be reported to the Regulator immediately, with a copy to the Biosafety Committee – see clause 6.2 below).**

Any accident involving injury or contamination to staff, students or visitors must be reported to the Human Resources Office using the *Charles Sturt University Accident/Incident Report Form* available from the Web (**NB:** This form is a separate one to BSC 1).

Biological spill kits

All facilities conducting work with potentially biohazardous materials shall store and maintain a *Biological Emergency Spill Kit* (conveniently located close to, but *outside*, the laboratory in a location known to all staff).

As a minimum, this kit shall contain:

- 'DO NOT ENTER' signs;
- 'BIOHAZARD' signs;
- suitable supplies of disinfectant (see clause 6.2 below for recommended disinfectants);
- absorbent materials;
- protective clothing including spare laboratory coats (preferably disposable, hydrophobic coveralls), rubber boots or overshoes and gloves;
- appropriate containers, including biohazard bags; and
- barrier tape.

Additional equipment may need to be included where the particular facility conducts work with Risk Group 2 micro-organisms requiring special precautions; for example, respirators.

Planning for the control of spillages is vital. **All staff, especially new staff, working in containment facilities shall read and understand the Standard Operating Procedures for the facility, and acknowledge this fact by signing the Staff Training Record Sheet accordingly.**

Again, it must be emphasised that a detailed Risk Assessment should be undertaken before the work commences. This process will highlight any special procedures or equipment necessary.

Emergency contact numbers

Low risk spillages may often be cleaned up immediately with a paper towel soaked in an effective chemical disinfectant. In the event of a high risk spillage outside of a biological safety cabinet, the situation becomes a lot more complex.

Should a high risk spillage occur, contact university security and the local hazmat team immediately.

Campus	Security	Hazmat Team
Wagga Wagga	32288	6921 3022
Bathurst	84999	6332 5634
Albury	16888	6021 3174
Thurgoona	19888	

Procedures for dealing with incidents and accidents

Procedures for dealing with low risk spillages

In the event of a Low Risk Spillage within a biological safety cabinet, or within an appropriate level containment facility for the micro-organism involved (see definition of Low Risk above):

- ensure that the cabinet remains operating to remove aerosols;

- place absorbent material soaked in disinfectant over the spill and leave for 10 minutes;
- disinfect gloved hands and remove gloves in the cabinet;
- if clothing is contaminated, remove for sterilisation;
- wash hands and arms;
- put on clean gloves and laboratory coat for remainder of clean up;
- remove any sharp objects with forceps and place in sharps container, soak up excess fluid with absorbent material and discard into a container for sterilisation (but *do not autoclave* materials soaked with *hypochlorite solution* due to the risk of toxic gas being produced. This material should be placed into a metal pan for disposal). Discard any solid material, petri dishes and culture bottles into an appropriate container;
- wipe down floor, cabinet work zone and other equipment with fresh disinfectant solution (see clause 6.2 for recommended disinfectants);
- consider formaldehyde fumigation of the cabinet;
- report spill to supervisor and submit a Biological Accident/Incident Report (using form BSC 1 – see clause 3) to the Biosafety Committee within 24 hours.

Procedures for dealing with high risk spillages

In the event of a High Risk Spillage:

- avoid breathing the aerosol, warn all other staff and leave the facility immediately;
- if possible, try to avoid travelling too far into other areas to prevent contamination;
- close the door and place the 'Do Not Enter' and 'Biohazard' signs on it;
- remove the laboratory coat and any other clothing suspected of being contaminated and place in a biohazard bag;
- if shoes are suspected of being contaminated, remove them also and place in a separate biohazard bag;
- if material has soaked through clothing, take full emergency body shower. Otherwise, wash hands and face thoroughly and put on clean laboratory coat;
- report spill to supervisor, and stay out of area for at least 30 minutes to permit aerosol particles to be dispersed;
- consider isolating ventilation system;
- assemble *biological spill clean up team* of three: one to direct procedure, others to clean up;
- put on laboratory coats, rubber boots/overshoes and gloves. Respirators and eye protection may also be required if a high risk infectious material is involved;
- determine the area of contamination;
- carefully pour an appropriate disinfectant, such as hypochlorite (5000 mg/L chlorine) or iodophor (8000 mg/L iodine) around the spill so that it mixes slowly with the contaminated material;
- place paper towels saturated with disinfectant over the spill and wait at least 10 minutes;
- remove any sharp objects with forceps and place in sharps container, and transfer all contaminated material to a metal pan for disposal (NB: *do not autoclave materials soaked in hypochlorite solution*);
- disinfect the area surrounding the spill site with fresh disinfectant solution;
- all members of the clean up team should then wash boots, discard respirators and gloves and autoclave laboratory coats prior to leaving the area;
- submit a Biological Accident/Incident Report (using form BSC 1 – see clause 3) to the Biosafety Committee within 24 hours. **If the spillage has involved GMOs, the Biosafety Committee shall forward the report to the OGTR.**

NB: If there is a risk to human health or the environment from the unintentionally-released GMO (such as a needle-stick injury), the accident must be reported to the Regulator immediately (Facsimile: (02) 6271 4202 or Email: ogtr@health.gov.au), with a copy to the Biosafety Committee – see clause 3 above). This information will also be include in the University's Annual Report to the Regulator.

In addition, any accident involving injury or contamination to staff, students or visitors must be reported to the Human Resources Office using the *Charles Sturt University Accident/Incident Report Form* available from the Web (**NB:** This form is a separate one to BSC 1).

Additional precautions where GMOs are involved

All staff shall carefully follow the appropriate conditions for physical containment outlined in the latest edition of the OGTR's "*Guidelines for Certification of Facilities/Physical Containment Requirements*" (available from the web) to minimise the chance of a spill or other unintentional release occurring.

In addition, to minimise the risk of an unintentional release of GM material *during transport* (this may include moving the material from one PC2 facility to another at the University) staff must ensure that they adhere strictly to the conditions outlined in the latest edition of the OGTR's "*Guidelines for the Safe Transport of GMOs*" (available from the web).

References

The following references were used in the compilation of these procedures:

1. The Australian Standard AS 2243.3 (2002): "Safety in Laboratories – Microbiological Aspects and Containment Facilities".
2. Haski, R (2001), "The Laboratory Safety Manual", CCH Australia Limited.
3. ANU Occupational Health & Safety Unit (2002), "The Australian National University Biological Safety Manual".

4.2 Quality assurance procedures

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Quality Assurance is a necessary component of occupational health and safety at the University. To ensure that 'quality' (in the case of this Manual, quality of biological safety) is maintained and improved upon in the future, a Quality Assurance Program needs to be formalised. The establishment of the Australian University Quality Agency (AUQA) by the Commonwealth and State Governments, which will be conducting quality audits of all publicly-funded higher education institutions in Australia over the next few years, and the requirements of the Commonwealth *Gene Technology Act (2000)* and *Gene Technology Regulations (2001)*, mean that Charles Sturt University must ensure that it has effective, documented quality assurance processes in place.

The University *Biosafety Manual* contains guidelines, procedures and policies which are designed to ensure that biological safety at the University is maintained at all times. *Verifying* that these policies and procedures are being complied with, through regular auditing, is an important quality assurance role of the Biosafety Committee.

Quality assurance responsibilities of the Biosafety Committee

The Charles Sturt University Biosafety Committee has been fulfilling a quality assurance role for the *Wagga Wagga campus* in the area of biological safety since 1992, and for the University as a whole since its formal establishment by the Board of Governors (as a *University-wide* Committee) on 17 August 1995 (BG 95/129). The Committee was originally constituted to be in accordance with the Genetic Manipulation Advisory Committee (GMAC) Guidelines; its Membership and Terms of Reference were amended on 30 May 2002 to ensure compliance with the Gene Technology legislation.

Auditing: Certified facilities

The Biosafety Committee shall conduct inspections of all *certified* containment facilities at Charles Sturt University **annually** to ensure compliance with the requirements specified in the latest edition of the *Guidelines for Certification of Facilities/Physical Containment Requirements* (Office of the Gene Technology Regulator [OGTR]). Inspection teams shall be chaired by an appropriately trained and experienced person who, in most cases, shall be the biocontainment expert member of the Committee.

Inspection reports shall be prepared and considered by the Biosafety Committee; recommendations for improvement shall be forwarded to the respective Heads of School and Facility Managers for action and to the Pro-Vice-Chancellor (Research and Graduate Training) for information. **Final reports shall be forwarded annually to the OGTR.**

Ad hoc inspections of certified containment facilities shall be conducted whenever the situation warrants it.

Copies of all inspection reports shall be maintained by the Executive Officer of the Biosafety Committee.

Auditing: Other containment facilities

The Biosafety Committee shall also conduct an inspection of all *other* containment facilities (PC1 and PC2 [microbiological only]) on a regular basis (every two years) to ensure that these facilities comply with the requirements outlined in the latest edition of the Australian Standard AS 2243.3 – *"Safety in Laboratories – Microbiological Aspects and Containment Facilities"*.

Inspection reports shall be prepared and considered by the Committee; recommendations for improvement shall be forwarded to the relevant Heads of School/Centre Directors and Facility Managers for action (if required) and to the Pro-Vice-Chancellor (Research and Graduate Training) for information as indicated at clause 1.1.1.

Record keeping and the maintenance of registers

The Biosafety Committee shall convene four formal meetings each year, and special meetings (including sub-committee meetings) as required. Copies of Minutes of all formal meetings shall be maintained by the Executive Officer, with original Minutes and agendas held by the University Regional Archives.

The Committee shall maintain a Register of all Exempt Dealings, Notifiable Low Risk Dealings (NLRDs) and Licensed Dealings undertaken at the University. It shall also maintain a Register of All Personnel Working in Containment Facilities at the University, both certified and non-certified facilities. Another Register of Micro-organisms of Risk Group 2 and Above held in facilities at the University shall also be maintained.

The Registers will maintain their currency by the Executive Officer of the Committee distributing copies of the various Registers to all relevant Schools, Centres and Divisions at the University **annually, in June each year.**

The responses (including copies of Staff Training Record Sheets) shall be then be reconciled with relevant reports from the Biosafety Database and – following discussion at a Biosafety Committee meeting and consultation with facility managers, if necessary – the Registers (database) shall be updated accordingly.

The Committee shall submit an **Annual Report each year** to the OGTR, which shall include:

- membership of the Committee (including member qualifications and positions held);
- current exempt, NLRDs and licensed dealings being conducted;
- certified facilities; and
- any contraventions of the Gene Technology legislation (this will *be in addition* to an immediate report at the time of discovery during facility inspections).

Internal checking of applications to the Regulator

All applications for licences, notifications for NLRDs, applications for certification of facilities and *any other dealing* with Genetically Modified Organisms (GMOs) **must be submitted in the first instance to the Biosafety Committee** for consideration and recommendation for approval. The Committee shall evaluate each proposal to undertake a GMO dealing which it receives, and shall provide copies of Evaluation Reports to the OGTR if required.

Development and promulgation of biosafety policies, procedures and guidelines

Another of the responsibilities of the Biosafety Committee is to both produce, and promulgate, a *Biosafety Manual* incorporating guidelines, policies and procedures which are intended to minimise the risk of infection or injury arising from contact with biohazardous material.

The following procedures shall be followed to ensure that amendments and additions to the Manual are approved in the required manner and promulgated to all appropriate staff and students at the University:

- *Substantial amendments to guidelines and procedures* (and minor amendments to policies) shall be forwarded to the Pro-Vice-Chancellor (Research and Graduate Training) [following discussion by the Biosafety Committee] for approval, prior to incorporation into the electronic version of the Biosafety Manual on the Web;
- *Minor amendments to guidelines, procedures and forms* shall be approved by the Biosafety Committee;
- *Substantial amendments to policies* shall be forwarded (after discussion by the Committee) to the Pro-Vice-Chancellor (Research and Graduate Training) *for transmission to the University Council* for approval, prior to being incorporated into the electronic version of the Manual on the Web;
- The Executive Officer shall notify all appropriate staff and students of any changes to the Manual approved by the Committee, the Pro-Vice-Chancellor (Research and Graduate Training) or the Council during the year, following each meeting, and shall advise them that the up-to-date, amended version of the Manual is available electronically at the link on the Committee's Home Page on the Web;

- The Executive Officer shall organise hard-copy reprints of the amended Manual and circulate them to all appropriate persons at the University annually, following the final Committee meeting of the year.

Quality assurance responsibilities of Heads of School/Centre Directors/Containment Facility Managers

Heads of School, Centre Directors, Containment Facility Managers and other appropriate supervisors shall be responsible for conducting the following *facility-specific* quality assurance procedures, which must be fully documented and available for future audits and/or OGTR inspections:

- **Procedures for training staff dealing with GMOs:** Staff Training Procedures are outlined in detail elsewhere in this Manual. All staff currently or potentially involved in gene technology work shall receive **induction training** which includes information on the Gene Technology legislation and the requirements for their particular facility as described in the latest edition of the *Guidelines for Certification of Facilities/Physical Containment Requirements*. Standard Operating Procedures, or 'Facility Manuals', shall be written for all facilities, or groups of facilities. Copies of these documents shall be submitted to the Biosafety Committee for approval. All staff and their supervisors shall sign *Staff Training Record Sheets* confirming that procedures have been understood and can be performed competently. **Copies of these sheets shall be forwarded to the Executive Officer of the Biosafety Committee annually, in June, to facilitate the updating of the relevant Register, and shall also be maintained in each facility for inspection during the annual audits** (see also clause 1.2 above).

Annual **refresher courses** for all staff in the OGTR requirements shall also be conducted, and signed off in the Staff Training Record Sheets.

- Autoclaves and biosafety cabinets shall be inspected at least **annually** by NATA accredited technicians or appropriately qualified staff (with records of qualifications). **Records of these inspections must be retained for future audits.**
- *Prior to any Maintenance Work being undertaken* within or to a biological facility, written clearance shall be provided (which will include a statement indicating that basic biological safety instruction had been imparted). Where the facility is a certified PC2 facility, maintenance and service personnel shall be made aware of any potential hazards associated with GMO dealings conducted in the facility. All surfaces and equipment shall be decontaminated before any maintenance is carried out.

4.3 Clearance procedures for maintenance work to biological facilities and fixtures

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Prior to any maintenance work being carried out in a Biological Facility, either to the facility itself, to the fixtures within the facility or associated services, *written clearance* must be obtained from the appropriate Facility Manager.

This clearance shall be provided using a duly completed copy of the form "*Clearance for maintenance work within/to a biological facility*" (BSC 2), see Appendix 5 (also available from the web).

As well as certifying that the particular facility is safe for entry, the letter shall also indicate that basic instruction in biological safety has been provided by the Facility Manager.

Where the facility is a certified PC2 Facility, maintenance and service personnel shall be made aware of any potential hazards associated with GMO dealings conducted in the facility. The Facility Manager shall ensure that all surfaces and equipment are decontaminated before any maintenance is carried out.

A copy of the clearance letter shall be retained by the Facility Manager for audit purposes.

4.4 Procedures for purchasing/acquiring (and notification of arrival of) micro-organisms of Risk Group 2 and above

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Prior to bringing any micro-organism of **Risk Group 2 or above** onto Charles Sturt University (CSU), approval from the Biosafety Committee (BSC) **must** be obtained. This includes purchases *or any other means of acquiring the Risk Group 2 or above micro-organism* such as loans or donations from other departments or institutions.

To obtain BSC approval for the *purchase* of a Risk Group 2 or Above Micro-organism, the applicant shall:

- complete the *white-coloured* copy of the “Application to Purchase/Acquire Micro-organisms of Risk Group 2 and Above” form. This form is located in the triplicate book of forms held in each certified PC2 Facility, each PC2 (Microbiological only) facility and by the BSC Executive Officer;
- forward the completed form to the Presiding or Executive Officer of the BSC, together with a *copy* of the Purchase Requisition form, for approval (after consideration, the Presiding/Executive Officer shall endorse the form and forward a *copy* to the applicant with a BSC approval number);
- upon receipt of an approved copy of the form, forward it – together with the *original* of the purchase requisition – to the Purchasing Officer, Division of Financial Services.

To obtain BSC approval for the *acquisition* of a Risk Group 2 or Above Micro-organism, the applicant shall:

- complete the *white-coloured* copy of the “Application to Purchase/Acquire Micro-organisms of Risk Group 2 and Above” form. This form is located in the triplicate book of forms held in each certified PC2 Facility, each PC2 (Microbiological only) facility and by the BSC Executive Officer;
- forward the form to the Presiding or Executive Officer of the BSC for approval.

After consideration, the Presiding/Executive Officer shall endorse the form and forward a copy to the applicant with an BSC Approval Number.

Notification of arrival

For a number of reasons, there may be a time delay between the initial ordering of a Risk Group 2 or above micro-organism and its subsequent delivery to the University. In order to keep an accurate record of all such micro-organisms held at the University, it is important that the applicant advises the BSC when the micro-organism ordered is actually delivered.

Upon the *arrival* of a Risk Group 2 or Above Micro-organism, the licence-holder shall:

- complete the *blue-coloured* copy of the “Application to Purchase/Acquire Micro-organisms of Risk Group 2 and Above” form (located in the triplicate book of forms held in each certified PC2 Facility and each PC2 (Microbiological only) facility);
- forward the form to the Executive Officer of the BSC so that the Register may be updated; and
- attach a label to the micro-organism’s container, identifying it with the BSC Approval Number (along with the other usual details such as name, date, etc.) prior to use.

4.5 Introduction to gene technology legislative requirements for new appointees and Standard Operating Procedures (SOP) for GMO dealings

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Introduction

Those projects that utilise genetic engineering/manipulation technologies to generate recombinant DNA and Genetically Modified Organisms (GMOs) now come under the auspices of the Federal Government's Office of the Gene Technology Regulator (OGTR) and all work is carried out in accordance with the Gene Technology Act 2000 and the associated **Gene Technology Regulations. The Gene Technology Regulations 2001 SR 106** provides further detail to the regulatory scheme for gene technology.

The Act does six key things. It:

1. establishes a statutory officer, the Gene Technology Regulator (the Regulator) to administer the legislation and make decisions under the legislation;
2. establishes a scientific committee, an ethics committee and a community committee from which the Regulator and the Ministerial Council on gene technology may request advice;
3. prohibits persons from dealing with GMOs (e.g. research, manufacture, production, commercial release and import) unless the dealing is:
 - exempt;
 - a Notifiable Low Risk Dealing (NLRD) – that is, contained research work which has been demonstrated to pose minimal risk to workers, the general public or the environment;
 - on the Register of GMOs; or
 - licensed by the Regulator.
4. establishes a scheme to assess the risks to human health and the environment associated with various dealings with GMOs, including opportunities for extensive public input;
5. provides for monitoring and enforcement of the legislation; and
6. creates a centralised, publicly available database of all GMOs and GM products approved in Australia (the Record of GMO and GM product dealings).

The Gene Technology Act requires institutions that conduct genetic manipulation work to set up an Institutional Biosafety Committee (IBC). The purpose of the IBC is to ensure that the Guidelines laid down by the OGTR are followed and it has the responsibility to carry out regular inspections of work-practices and facilities and assess proposals for new work involving recombinant DNA. An IBC has been established at Charles Sturt University to carry out the above functions.

For most of the work carried out at Charles Sturt University, the Regulations and Guidelines that relate to work under Physical Containment Level 2 (PC2) Laboratories most generally apply. In addition to the OGTR guidelines, procedures for PC2 facilities can also be found in the Australian Standards (AS/NZS 2243.1 and AS/NZS 2243.3, available from the web). Details of the construction and practices that apply to the operation of PC2 (and other) containment facilities can be found in the "*Guidelines for Certification of Facilities/Physical Containment Requirements*" (available from the web).

PC2 laboratories provide containment that rely primarily on the biological containment offered by the system being worked with, i.e. well characterised and widely used host-vector systems such as *E. coli* and pBR322 derived plasmids. However, containment is also reliant on a set of procedures that are followed in the normal day-to-day operation of the laboratory. It is therefore of utmost importance that you familiarise yourself with these laboratory procedures and make sure that you follow them. A summarised version of the relevant procedures for work in PC2 Laboratories is provided in Appendix 1.

The project supervisor should have a copy of the appropriate guidelines. If you have any queries that arise during the course of your work, then consult your supervisor and/or the guidelines. If these queries cannot be answered by reference to the Guidelines, then feel free to consult a member of the IBC (contact details are available from the IBC website – see Biosafety Manual Section 1.3).

Standard Operating Procedures for Physical Containment Level 2 GMO Dealings

Operating procedures for PC2 laboratories can be found:

- in the OGTR's "Guidelines for Certification of Facilities/Physical Containment Requirements";
- in the in the Australian Standard (AS/NZS 2243.1 and AS/NZS 2243.3);
- on the signs next to the door on all PC2 laboratories (abbreviated version);
- *via* the OGTR's web site

Also helpful is "Safety Practices in PC2 Laboratories: Genetic Manipulation Advisory Committee".

While the basic procedures that are to be followed while working in PC2 laboratories are provided in the above places and summarised in Appendix 1, aspects of these procedures and how they specifically apply within the Charles Sturt University are covered more fully below. The same numbering system has been followed in the following section as that found in Appendix 1.

Personal Protective Clothing and Equipment

- b. *Closed footwear shall be worn.* Thongs and open-toed sandals are not appropriate footwear for work under any laboratory conditions.
- d. *Safety glasses, face shields and other protective devices shall be worn where appropriate to protect eyes and face from splashes and other hazards.* Protective eye-wear should be worn when any hazardous material is being handled e.g. phenol, acids, strong bases etc. Safety glasses are available from the Store and it is recommended that all personnel have at least one pair of these for their personal use.
- e. *Gloves should be worn when handling infectious materials. Hands shall be thoroughly washed after removal of the gloves, as minute holes may permit the entry of microorganisms. Gloves shall not be reused and shall be discarded with laboratory wastes.* Several types of disposable gloves are available and staff should find those that best suit their own needs. Bear in mind that with some of the gloves there have been cases of allergic reactions to the lubricating powder used in them. If you have any such symptoms, then test some of the other gloves for suitability. Note, there are also inner gloves (cotton) available that can be worn under the disposable gloves.

Remember:

- Gloves should be worn at all times when carrying out recombinant DNA work and should be disposed of through the bio-waste system. Gloves worn for other purposes eg handling of chemicals etc., as they can be construed as "contaminated" should also be disposed of through the bio-waste system.
- Wash your hands thoroughly after removing your gloves.
- It should also be noted that when moving between laboratories, gloves should not come into contact with door handles allowing the inadvertent transfer of infectious and/or hazardous substances to the door handle.
- f. *Goggles or visors shall be used where appropriate to protect eyes from contaminated or dangerous materials, or from damage by ultraviolet light (see AS 1336 and AS/NZS 1337). Plumbed eyewash stations, mounted at an easily accessible height, should be provided. If these are not available, it is recommended that single-use packs of sterile eye treatment fluids be provided.* Staff should familiarise themselves with the nearest eyewash station and the method of operation.

Work Practices

- g. *Food or drink for personal consumption shall not be brought into the laboratory or stored in laboratory refrigerators. Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited in laboratories. The smelling and sniffing of bacterial cultures for odours is prohibited.*

NOTE: Hands, pens and pencils, which can become contaminated from dirty surfaces, liquids and aerosols, should be kept away from the face.

- i. *Cultures shall be clearly identified, dated and appropriately stored. Cultures should not be stored for long periods on the bench, but should be transferred to a dedicated storage area, such as a refrigerator or part of a cold room.* All of the refrigerators that contain manipulated

DNA and/or its derivatives are clearly marked with yellow Biohazard labels. Needless to say, the storage of food and drink in any laboratory refrigerators/freezers is not allowed under existing health and safety Guidelines.

- m. *Work benches shall be decontaminated following spills, and also when work is completed.* Work benches should be decontaminated at the completion of each day's work with freshly made disinfectant Bleach solution (10% v/v of household bleach) or 70% ethanol can be used as disinfectant for recombinant bacterial host/vector systems. Undiluted ethanol is not suitable as a disinfectant as it does not lyse bacterial membranes.
- n. *Special precautions shall be taken to ensure that reading and writing materials do not become contaminated.* If your laboratory is fitted with carrels then this will be less of a problem than in those laboratories without them. If you do not have a carrel, there are a few simple rules that will allow you to keep reading/writing materials away from potential sources of contamination:
- don't store laboratory notebooks, catalogues, etc. at bench level – make sure they are raised well off the bench level – and preferably away from other reagents;
 - If you do have a spill, make sure that it is cleaned up properly and that any necessary decontamination is undertaken.
- q. *Laboratory personnel shall receive instruction and training, with regular updates, in handling pathogens.* While the intent of the guidelines is to indicate human pathogens, it should also be borne in mind that other groups work on plant/animal/insect pathogens. Cross-contamination between laboratories can, at best, lead to the loss of large amounts of work and time. If you are working with any microbe, then check with your supervisor what special precautions need to be taken to minimise the risk of such contamination occurring.
- r. *After use, the needle and syringe shall be placed in a puncture-resistant container (see AS 4031) for disposal, preferably by incineration. Before disposal, needles shall not be removed, bent, sheared, or replaced in a sheath or guard, unless the recapping/removal procedure can be carried out by a safe method with suitable equipment. Particular care shall be taken when using syringes and needles as needle-stick injuries constitute a large portion of laboratory accidents.* Suitable containers should be available for the disposal of "sharps" in all laboratories. The following procedure should be followed:
- When full, the container should be sealed and then autoclaved. NOTE: the container should be well sealed with autoclave tape before treatment to clearly indicate that the materials have been autoclaved prior to disposal;
 - After autoclaving the whole container should be disposed of through the University's Waste disposal system (placement of autoclave tape on the exterior of the container to indicate sterilization is advisable).
- x. *Microbiological waste shall be incinerated, or autoclaved before disposal. However, all waste involving genetically manipulated organisms shall be steam sterilised before disposal.* In addition to these instructions, users should be aware of the risks involved with all chemicals used in laboratories, their storage and safe disposal.

ALL waste (with the exception of general paper waste) generated in PC2 laboratories should be disposed of via the autoclave. Under no circumstances should any material that could be construed as having been used for recombinant DNA work e.g. Gilson tips, Eppendorf tubes, petri dishes etc. etc. be disposed of via the normal waste route – irrespective of whether or not it has been used for recombinant DNA work.

Each laboratory should have dedicated bin that is clearly labelled with the universal (yellow) Biohazard sign to contain the Biohazard bag in use. Cleaners should be instructed that bins that are marked with the universal biohazard sign are not to be emptied. It is the responsibility of each laboratory to ensure that its bio-waste is disposed of in the correct manner.

Material should be transported to the nearest autoclave in a sealed Biohazard waste-bag marked with autoclave tape, inside an unbreakable container. The weight of the material should be recorded before and after autoclaving in a logbook kept adjacent to the autoclave. Make sure when autoclaving that whatever has been used to seal the bag has been loosened to allow the steam to penetrate into the bag. Each autoclave run should include a *Thermalog S* steam sterilisation integrator. If the dark bar has not entered the SAFE zone,

proper criteria for sterilisation have not been achieved and the material should be re-autoclaved and/or the proper functioning of the autoclave should be checked.

After autoclaving, Biohazard waste-bags should be sealed in suitable green (or black) garbage bags and disposed of *via* the normal waste-disposal routes. The *Thermalog S* steam sterilisation integrator should be retained and placed in the autoclave log.

Disposal of glass presents hazards akin to the disposal of “sharps”. Following autoclaving the material may be disposed of through the normal garbage disposal system.

- z. *Facilities, separate from the workbench, should be provided for reference documents and for writing reports.* Staff should take care when moving notebooks etc. between the laboratory and their allocated desk area so that they do not inadvertently transport infectious/recombinant material between the two locations.
- a1. *Personnel who wish to transfer material between institutions are advised to pay particular attention to the various statutory regulations regarding transport of biological materials that may be regarded as infectious.* Details of the regulations regarding the transport of GMO materials can be found in the Guidelines. Basically these amount to:
- containing the GMO in a primary sealed container;
 - securing that container in a secondary sealed unbreakable container and,
 - ensuring that the outside of the second container is clearly labelled with the Universal Biohazard sign and the contact details of the consigner/consignee.

REMEMBER: These procedures apply **even if the material is being transported between PC2 labs** (i.e. across corridors, foyers and stairwells etc.) in the same building.

- c1. *All of the above procedures relate to work in a PC2 designated area whether genetic manipulation work is in progress or not.* The procedures discussed in this document apply all of the time that you are working in a PC2 laboratory – whether you yourself are carrying out genetic manipulation work or not. Procedural requirements do not stop at 5 o'clock, over the weekend or on public holidays. The above also means that DNA manipulation work and storage of recombinant materials can only be carried out in laboratories that have been certified as PC2 or above.

4.6 Staff training

Originally approved by the Pro-Vice-Chancellor (Research & Graduate Training) on 30 August 2002

Version: 28 August 2002

Next Review: August 2004

Administered: Centre for Research & Graduate Training

Introduction

In order to meet the requirements of the *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* and the various guidelines produced by the Office of the Gene Technology Regulator (OGTR), all staff currently or potentially involved in gene technology work should receive **induction training** that includes information on the new Gene Technology legislation.

All other staff (i.e. staff not directly involved in gene technology work) should also receive induction training which outlines the essential minimum practices required in a facility handling biological materials. In addition to the facility rules and familiarity with the various standard operating procedures, this training should also include an introduction to the other University Biosafety policies, procedures and guidelines found elsewhere in this Manual.

All staff working in *certified facilities* (i.e. laboratories or plant houses certified by the OGTR as meeting all of the requirements for Physical Containment Level 2 [PC2] (see below)) at Charles Sturt University (all campuses) should have read and understood the relevant *Physical Containment Requirements* (specifically relating to work practices) as described in the *Guidelines for the Certification of Facilities/Physical Containment Requirements* (available from the web).

In order to demonstrate that respective staff have received and understood such training, the OGTR would like to see evidence of **signed records** of those staff who have been trained, when that training took place and the nature of the training received. **It is recommended that each Facility Manager should hold these records (known as Staff Training Record Sheets) and have them stored in a place accessible when the facility is inspected. Inspections of all certified facilities must be undertaken at least annually, and reports provided to the Regulator.**

It is recommended that Standard Operating Procedures (SOP) be written for each facility or each group of similar facilities, that all staff have read and understood the SOP for their facility and provided a **signed statement** confirming that they have read and understood them. Supervisors shall *also* sign these Staff Training Record Sheets when they are confident that the staff member has understood and can competently perform each of the facility SOP. SOP shall be written for all major laboratory equipment, such as Biosafety Cabinets and Autoclaves. Good laboratory practice requires that a copy of the SOP be prominently displayed in each facility. The SOP shall incorporate the work procedures ('specific conditions') outlined in the *Guidelines for the Certification of Facilities/Physical Containment Requirements*. Copies of these documents shall be provided to the Biosafety Committee for attachment to the applications for certification of the facilities when they are submitted to the OGTR. The Committee has the right to periodically sight the records maintained in each facility for the purposes of compliance with the regulations contained in the Act.

Annual refresher courses for all staff in the OGTR requirements for each particular facility are also required, and should be signed off on the Staff Training Record Sheets.

Source: Office of the Gene Technology Regulator (2000): Canberra, ACT.

Classification of facilities

PC1: Suitable for student and undergraduate teaching laboratories. Suitable for work with micro-organisms where the hazard levels are low and where the laboratory personnel can be adequately protected by standard laboratory practice. The organisms used are not known to cause disease in healthy adults (i.e. organisms are in Risk Group 1). Work may be carried out on an open bench. Specimens that have been inactivated or fixed may be handled in a level PC1 laboratory.

Any **exempt dealings** with GMOs must be conducted in a facility which meets, as a minimum, the requirements for this level of containment (PC1), as outlined in the Australian Standard AS 2243.3 (2002): "Safety in Laboratories – Microbiological Aspects and Containment Facilities". The Biosafety Committee shall inspect all PC1 and PC2 (microbiological only) facilities at the University to ensure that they meet the requirements outlined in the Standard.

PC2: A facility with its practices and equipment applicable to clinical, diagnostic, industrial, teaching and other premises where work is carried out with micro-organisms or material likely to contain micro-organisms which may be present in the community, where the micro-organism may be associated with animal, plant or human disease of moderate severity (e.g. Risk Group 2 micro-organisms). With good microbiological techniques, work with these agents may be carried out on the open bench.

Notifiable Low Risk Dealings (NLRDs) with GMOs must be conducted within a contained facility *which has been certified by the OGTR* to at least this level.

4.7 Authorisation requirements for all PC2 Plant House personnel and for the transfer of living plants and tissue to another organisation

Originally approved by the Pro-Vice-Chancellor (Research & Graduate Training) on 5 June 2002

Version: 29 May 2002

Next Review: June 2004

Administered: Centre for Research & Graduate Training

Only persons *authorised* by the Biosafety Committee are permitted to enter PC2 Plant Houses.

Staff working in such facilities shall be trained in the OGTR physical containment requirements for PC2 plant houses (as indicated in the latest edition of the "*Guidelines for Certification of Facilities/Physical Containment Requirements*", available from the web), in addition to the normal plant house procedures, at induction.

Signed Staff Training Record Sheets for all plant house staff shall be submitted to the Biosafety Committee for authorisation of the persons concerned, and for the addition of their names to the Register of Users of the Facility.

Refresher courses for all staff in the OGTR requirements shall be conducted annually.

Prior to any *Living Plants or Tissue* being transferred from the facility to another organisation, approval shall be sought from the Biosafety Committee.

Appendix 1: Procedures for PC2 laboratories

A summary of the practices for PC2 laboratories as laid down in AS/NZ 2243.1 and AS/NZS 2243.3 and in the "Guidelines for Certification of Facilities/Physical Containment Requirements".

Personal protective clothing and equipment

- a. Protective clothing, preferably in the form of a theatre or wrap-around laboratory gown, shall be worn within the laboratory to afford protection to the front part of the body.
- b. Closed footwear shall be worn.
- c. Protective clothing shall be removed before leaving the laboratory area and shall be stored in facilities provided. Staff shall remove laboratory gowns and thoroughly wash hands and fingernails before moving to areas outside the laboratory, e.g. canteen, refreshment room or toilet.
- d. Safety glasses, face shields and other protective devices shall be worn where appropriate to protect eyes and face from splashes and other hazards.
- e. Gloves should be worn when handling infectious materials. Hands shall be thoroughly washed after removal of the gloves, as minute holes may permit the entry of micro-organisms. Gloves shall not be reused and shall be discarded with laboratory wastes.
- f. Goggles or visors shall be used where appropriate to protect eyes from contaminated or dangerous materials, or from damage by ultraviolet light. (See AS 1336 and AS/NZS 1337.). Plumbed eyewash stations, mounted at an easily accessible height, should be provided. If these are not available, it is recommended that single-use packs of sterile eye treatment fluids be provided.

Work practices

- g. Food or drink for personal consumption shall not be brought into the laboratory or stored in laboratory refrigerators. Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited in laboratories. The smelling and sniffing of bacterial cultures for odours is prohibited.

NOTE: Hands, pens and pencils, which can become contaminated from dirty surfaces, liquids and aerosols, should be kept away from the face.
- h. Significant spills and accidents shall be reported immediately to the laboratory supervisor. A written record of accidents shall be prepared and maintained.
- i. Cultures shall be clearly identified, dated and appropriately stored. Cultures should not be stored for long periods on the bench, but should be transferred to a dedicated storage area, such as a refrigerator or part of a cold room.
- j. Where work is carried out on the open bench, care shall be taken to minimise the production of aerosols.
- k. Care shall be taken to prevent the dissemination of material while flaming a wire loop, by drawing the loop gradually from the cooler to the hotter parts of the Bunsen burner flame, or by using a hooded or an electric Bunsen burner. Disposable loops may be used as an alternative.
- l. Mouth pipetting shall be prohibited. Rules for the correct use of pipetting devices and syringes shall be followed. Blowing out residual volumes from pipettes creates aerosols; therefore it is preferable to use pipettes calibrated to deliver.
- m. Work benches shall be decontaminated following spills, and also when work is completed.
- n. Special precautions shall be taken to ensure that reading and writing materials do not become contaminated.
- o. Labels shall not be moistened with the tongue. The use of self-adhesive labels is preferred.
- p. Access to the laboratory shall be limited to laboratory personnel and persons specified by the laboratory management. Laboratory doors should be normally closed when work is in progress.
- q. Laboratory personnel shall receive instruction and training, with regular updates, in handling pathogens.
- r. The use of syringes and needles shall be restricted to parenteral injection and aspiration of fluids from laboratory animals and diaphragm-capped bottles. After use, the needle and syringe shall be placed in a puncture-resistant container (see AS 4031) for disposal, preferably by incineration. Before disposal, needles shall not be removed, bent, sheared, or replaced in a sheath or guard, unless the recapping/removal procedure can be carried out by a safe method with suitable equipment. Particular care shall be

- taken when using syringes and needles as needle-stick injuries constitute a large portion of laboratory accidents.
- s. Laboratory staff shall advise maintenance and service personnel of the special microbiological hazards in the laboratory.
 - t. For manipulations such as shaking, mixing, and ultrasonic disruption, a biological safety cabinet or other equipment designed to contain the aerosol shall be used. A period of at least 5 minutes shall be allowed for aerosols to settle before opening homogeniser or sonicator containers in a biological safety cabinet (BSC). NOTE: Large items of equipment will interfere with the airflow pattern in a Class II BSC.
 - u. Care shall be taken when carrying material likely to contain live organisms between laboratories or to autoclaves within the building. Any container of viable organisms shall be transported within a second unbreakable and closed container which can be readily decontaminated.
 - v. Potentially contaminated re-useable glassware shall be autoclaved or chemically disinfected prior to washing and re-use. For chemical disinfection, pipettes shall be placed in a disinfectant solution, tip-first and fully immersed, to minimise the production of aerosols. If pipettes are to be autoclaved a detergent solution is acceptable.
 - w. Laboratory waste should be decontaminated prior to disposal. If desired, decontamination may be performed with household bleach that has been appropriately diluted (1/10 of household bleach which usually contains about 4 percent w/v (40,000 ppm) available chlorine).
 - x. Microbiological waste shall be incinerated, or autoclaved before disposal. However, all waste involving genetically manipulated organisms shall be steam sterilised before disposal.
 - y. Because airborne fungal spores can spread in a similar manner to aerosols, Petri dish cultures of fungi should be sealed with tape to prevent dispersal of spores which may be allergenic or contaminate other cultures. Where shedding of spores occurs, dedicated incubators should be allocated for specific use in fungal work.
 - z. Facilities, separate from the workbench, should be provided for reference documents and for writing reports.
 - a1. Personnel who wish to transfer material between institutions are advised to pay particular attention to the various statutory regulations regarding transport of biological materials which may be regarded as infectious.
 - b1. Wherever possible items should not be stored on the floor so that the floors can be easily cleaned.
 - c1. All of the above procedures relate to work in a PC2 designated area whether genetic manipulation work is in progress or not.

Appendix 2: Guidelines to assist researchers in the completion of the Notifiable Low Risk Dealing (NLRD) form (including *re-notification* of a NLRD)

Refer to Chapter 5 of the “*Handbook on the Regulation of Gene Technology in Australia*” (available from the web)

A checklist for completion of the form is located at the end of this chapter.

All questions must be answered with the appropriate level of detail or justification provided. If questions are answered in an attachment, refer to the attachment’s title and the section(s) and page(s) in the relevant section on the application form. Put an answer in every box, even if the answer is N/A (not applicable).

Please do not make unsupported statements. All statements should be supported with references to published work, unpublished data, expert advice etc. You are encouraged to include with your application copies of any relevant literature that is referenced in the application, as this will greatly facilitate the application assessment process.

When framing the **Title of your Project**, do so in a manner which does not reveal information which you may wish to remain confidential (for example, ensure that the title does not reveal any information concerning the parent organism). The Gene Technology legislation enables the Public to access the Record of [most] GMO and GMO Product Dealings approved by the Regulator (or product regulators) in Australia. This record includes the title of the NLRD, the name of the University where the dealing will occur, the date of the notification of the dealing to the Regulator and what kind of NLRD is involved. If you believe that *part of your* application/notification is confidential commercial information (CCI), you may apply to the Gene Technology Regulator (GTR) for a **CCI declaration** over that information (form available from the Executive Officer or from the OGTR Web-site). *Please note that the Regulator must consider the request for a CCI declaration against the Public Interest, and if she feels that the latter outweighs the arguments put forward by the applicant, the application will **not** be approved.* If the Regulator refuses the CCI application, you have the option of withdrawing the NLRD notification.

Date of Commencement: If the facility in which the work is to proceed has not been certified by the Regulator, work may not commence until certification has been approved. In such circumstances, the following text should be entered onto the form: “Work will not commence until the ...[Name of Facility]... has been certified by the Regulator”.

Description of Proposed Dealing: Describe *what* you are planning to do and *why* you are doing it.

Purposes and Aims of Proposed Dealing: Describe the full sequence of events which you are planning to undertake in an attachment to the form.

Identification of Person, Persons or Class of Persons Proposing to undertake the NLRD: As there is currently no scope for varying an NLRD in the legislation, it was felt that “class of persons” would be added to the form to cover PhD or Honours students who *may* be working on the project in the future. Add this information to the form here if applicable.

Description of the GMO: - *Modified Trait:* identify **all** modified traits which were not present in the host organism prior to work commencing (e.g. coat colour in mice); not only the genes being assessed, but *also the selection/marker genes*;

- if using *more than one* GMO, copy the page and complete details for *each* GMO in the NLRD;
- *Parent Organism:* the biological source of the donor DNA.

Genetics of the GMO: - *Donor DNA* is where **all** the DNA originated (e.g. may include antibiotic-resistant genes as well as the gene of interest);

- *Vectors:* it is useful to supply a plasmid map here, especially for specialised vectors (but not necessary for those vectors freely available commercially);
- *Host/vector Systems for Exempt Dealings:* Part 2 of Schedule 2 of the GT Regulations has been re-printed in the enclosed extract from the Handbook (as **Box 4**). Whole animals/plants are not on this list. If the intended host/vector system is not on the list, tick ‘No’ and provide extra information.

Types of NLRD: This information will go onto the Public Record. Only enter *one* type of NLRD onto the form (If more than one type, you will need to fill out more than one form).

Risk Assessment Information: Do **NOT** say that there is “No Risk”. Provide *reasons* for a low level of risk;

- *Details of Risks:* if released unintentionally (for example, during transport), what are the risks?

Facility Details: Use the *same Facility name* as provided by the University Biosafety Committee to the Regulator (see list of certified facilities at Appendix 8);

- *Date of Certification:* Until the University's Facilities have been re-certified by the Regulator, this date will be the date of *deemed certification*, i.e. 21 June 2001;
- *Certification Number:* Leave this field blank until re-certification.

Other Risk Management Information: - *Transport:* Transport includes moving the GMO from one certified PC2 facility at the University to another. It even includes moving it down the corridor! Indicate that: "Transport will be in accordance with the Guidelines for the Transport of GMOs". (copy of these guidelines enclosed);

- *Disposal:* Detail disposal arrangements for the GMO as indicated in Chapter 7, Part A of the "**Guidelines for Certification of Facilities/Physical Containment Requirements**" (e.g. that all microbiological waste should be steam sterilised [in an autoclave] before disposal or chemically disinfected) [available from the web], or as indicated at clauses 9.1 and 9.2 of Section 9 of the Australian Standard AS 2243.3 – 2002: "**Safety in Laboratories – Microbiological Aspects and Containment Facilities**" (e.g. as above, with the addition of high temperature incineration), or *other ways which would satisfy the Regulator (describe these other means in detail)*;
- *Remedial Action if Accidentally Released:* The Regulator must be notified **immediately** if any *unintentional release* occurs, such as a needle-stick injury. This information must also be referred to the Biosafety Committee, using the Biological Accident/Incident Report (form BSC 1 - see Appendix 4 or available from the web), and to the Human Resources Office using the Charles Sturt University Incident Report Form (available from the web) within 24 hours.
- *Other Actions/Precautions to Minimise Risks:* If you feel that no other action is required, **justify this** (e.g. "All personnel working on the project within the certified facility will receive training to minimise any risk").

Additional Information: If the parent organism is a weed, *cite references in the attachment.*

Signatures: The *primary delegate* of the Vice-Chancellor is currently the Pro-Vice-Chancellor (Research and Graduate Training), Professor Paul Burnett; in case of his absence, the Dean of the Faculty of Science and Agriculture (Professor Jim Pratley) is currently his delegate.

Future Variations to NLRDs: As there is no scope in the legislation to vary a NLRD, generally changes will necessitate submission of a *new* NLRD to the Biosafety Committee. If only very minor changes are proposed, contact the Executive Officer of the Committee for further advice.

Appendix 3: Guidelines to assist researchers in the completion of the Exempt Dealing form

There are two versions of the form: *Exempt Dealing Evaluation Report* – one for research proposals and the other for undergraduate classes and practicals – see Appendix 6 and Appendix 7. These forms are also available from the web.

Refer to Chapter 4 of the “*Handbook on the Regulation of Gene Technology in Australia*” (available from the web).

A checklist for exempt dealings with GMOs is located at the end of this chapter.

All questions must be answered **in detail** to enable the Biosafety Committee (IBC) to confirm that your dealing has been correctly classified. If necessary, expand on your answers to questions in an attachment, and refer to the attachment’s title and the clause(s) and page(s) in the relevant section on the evaluation form. If you have doubts concerning the classification of your dealing, consult the Presiding Officer of the IBC in the first instance, **or the OGTR on 1800 181 030**.

Please do not make unsupported statements. All statements should be supported with references to published work, unpublished data, expert advice etc. You are encouraged to include with your form copies of any relevant literature that is referenced in the application, as this will greatly facilitate the application assessment process.

Class of GMO: Provide *details* on the strain or type of organism involved. The class should be selected from the following groupings:

- Animal;
- Protozoa;
- Fungi;
- Algae;
- Bacteria;
- Virus; or
- Plant.

Modified Trait: Select one or more of the following classes of modified trait and *include details*:

- Virus resistance;
- Fungal resistance;
- Bacterial resistance;
- Disease resistance;
- Pest resistance;
- Herbicide tolerance;
- Antibiotic resistance;
- Pesticide resistance;
- Abiotic stress resistance;
- Altered agronomic characteristics;
- Altered horticultural characteristics;
- Altered nutritional characteristics;
- Altered physical product characteristics;
- Altered physiological characteristics;
- Altered pharmaceutical characteristics;
- Attenuation;
- Antigen expression;
- Protein expression;
- Growth factor expression;
- Altered biosensor characteristics;
- Altered bioremediation characteristics;
- Altered biocontrol characteristics;
- Reporter/marker gene expression;
- Immuno-modulatory protein expression;
- Other.

Details of Recombinant DNA (including Vector): Describe the gene, class of gene or recombinant DNA involved. Describe the vectors or methods used to transfer the donor DNA to the host. If symbols or numbers are used to name the vectors, include information regarding the origin and properties of the vector.

Facilities To Be Used: Please use the full name of the facility as used by the IBC (see *Register of Containment Facilities at Charles Sturt University* at Appendix 8), and include the room and building numbers and the campus involved. Please note that the Exempt Dealing must be conducted in a facility which, **as a minimum**, meets the requirements of the Australian Standard AS 2243.3: 1995 (“*Safety in Laboratories – Microbiology*”) for Physical Containment Level 1 (PC1).

For Undergraduate Class Practicals: Sessions in Which Practical Conducted: Some subject coordinators may wish to apply to have their practical conducted during a particular session over several years. Name the session.

Duration of Approval: Nominate the number of years (maximum of 3) for which you would like the approval to be valid before needing to reapply to the Committee. The Committee will approve this duration on a case-by-case basis, and the approval will be reviewed regularly.

Other Information: - *Practical Extract:* If your proposed dealing is an undergraduate classwork practical, it would greatly assist the IBC if you could attach a copy of the practical documentation to the form;

- *Waste Disposal:* Could you please also attach information describing your plans for waste disposal and – if the autoclave is not located within the containment facility – include a sketch plan, indicating the route to be followed to transport the materials to the autoclave. Include details on how you will transport the waste materials to the autoclave, i.e. in accordance with the *Guidelines for the Transport of GMOs* (available from the web).

Retain a copy of your form and all attachments, and forward the original to the Executive Officer, Biosafety Committee, for attachment to the next agenda. You will be notified of the IBC’s decision by electronic mail immediately following the meeting (with formal notification to be sent as soon as possible).



IBC Number: 223

Exempt Dealing Evaluation Report

Form BSC 3 (Version 2)
IBC Reference No

If you require more space please attach additional sheets (number of additional sheets attached.....)

1. Project Supervisor

2. Project Title

3. Exemption category (☑ applicable category)

- 1. Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal: (a) by the deletion or inactivation of the gene concerned; or (b) for mice that also carry a selectable marker gene – by the selectable marker gene.
- 2. Any dealing with a whole animal, if: (a) naked recombinant nucleic acid has been introduced into its somatic cells; and (b) the introduced nucleic acid is incapable of giving rise to infectious agents.
- 3. Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells: (a) are capable of giving rise to recombinant infectious agents; or (b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.
- 4. Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if: (a) the donor DNA: (i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and (ii) is not an oncogene; and (iii) does not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and (iv) does not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and (v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or (b) the donor DNA includes a viral sequence or viral sequences, but: (i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and (ii) is incapable of complementing a defect in the host/vector system.
- 5. Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of this Schedule.

4. GMO class and details ¹

5. Modified trait(s) class and details ¹

6. Details of recombinant DNA including vector ¹

7. Facilities to be used

Name
Building No Room No Level PC

8. Project dates

Start Finish

9. Waste disposal (describe)

10. Principal Investigator

Name:
signature date

11. IBC Declaration

The IBC has evaluated this dealing and agrees that it is an exempt dealing as specified by Schedule 2 of the Gene Technology Regulations 2001.
IBC Name: Charles Sturt University IBC (223)

Chair: name
signature date

Notes:
1. Refer to Guidelines



Exempt Dealing Evaluation Report (undergraduate classes)

Form BSC 4 (Version 2)
IBC Reference No

If you require more space please attach additional sheets (number of additional sheets attached.....)

1. Subject Coordinator ¹

2. Practical Title

3. Exemption category (applicable category)

- 1. Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal: (a) by the deletion or inactivation of the gene concerned; or (b) for mice that also carry a selectable marker gene – by the selectable marker gene.
- 2. Any dealing with a whole animal, if: (a) naked recombinant nucleic acid has been introduced into its somatic cells; and (b) the introduced nucleic acid is incapable of giving rise to infectious agents.
- 3. Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells: (a) are capable of giving rise to recombinant infectious agents; or (b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.
- 4. Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if: (a) the donor DNA: (i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and (ii) is not an oncogene; and (iii) does not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and (iv) does not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and (v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or (b) the donor DNA includes a viral sequence or viral sequences, but: (i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and (ii) is incapable of complementing a defect in the host/vector system.
- 5. Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of this Schedule.

4. GMO class and details ²

5. Modified trait(s) class and details ²

6. Details of recombinant DNA including vector ²

7. Facilities to be used

Name

Building No:..... Room No:..... Level: PC

8. Session(s) Autumn... Spring... Other...

9. Duration of approval 1 year... 2 years... 3 years...

10. Waste disposal (describe)

11. Subject Coordinator ²

Name:

..... signature date

12. IBC Declaration

The IBC has evaluated this dealing and agrees that it is an exempt dealing as specified by Schedule 2 of the Gene Technology Regulations 2001.
IBC Name: Charles Sturt University IBC (223)

Chair:

..... signature date

Notes:
1. Or person responsible for practical
2. Refer to Guidelines

Appendix 8: Register of containment facilities at Charles Sturt University**Certified containment facilities: Physical Containment Level 2 [PC2]****Wagga Wagga Campus**

Facility	Manager	Contact
Morell Laboratories (Bldg 10).....	Containment Lab (Room 229)	Mr Ken Simpson..... 6933 4032
	Biomed. Research Lab (Room 225)	“ “ “ “
	Isotope Lab (Room 228)	“ “ “ “
Sutherland Laboratories (Bldg 268).....	Plant Pathology Lab (Room 117).....	Dr Nigel Urwin 6933 2450
Gen. Microbiology Lab/Wine & Grape Research Lab (Bldg 406, Room 102).....	Mr Chris O'Connell.....	6933 4015
School of Agriculture Glasshouse D (Bldg 284)	Mr David Thompson.....	6933 2123

CAMBIA

Facility	Manager	Contact
CAMBIA Laboratory	Mr Leon Smith.....	6246 4536

Other containment facilities: Physical Containment Level 1 [PC1]**Albury-Wodonga Campus**

Facility	Manager	Contact
Science Lab (Bldg S21, Room 1.11)	Mr Jim Watt	6338 4373

Bathurst Campus

Facility	Manager	Contact
Physiology Lab (Bldg 601, Room 121) ¹	Ms Cheryl Kolbe.....	6051 6995
Anatomy Lab Complex (Bldg 621) ¹	Miss Diane Swain.....	6051 6966

Wagga Wagga Campus

Facility	Manager	Contact
Morell Laboratories (Bldg 10)	Teaching Lab (Room 251) ¹	Mr Ken Simpson..... 6933 4032
	Research Lab (Room 224)	“ “ “ “
	Teaching Lab (Room 233)	“ “ “ “
	Biology Teaching Lab (Room 211)	Mr Myles Ryan 6933 2356
Sutherland Laboratories (Bldg 268).....	Biology Teaching Lab (Room 125)	Ms Natalie Allison..... 6933 2350
	Soil Teaching Lab (Room 141)	“ “ “ “
	Plant Teaching Lab (Room 169)	“ “ “ “
	Inoculating Room (Room 107)	“ “ “ “
	Agronomy Teaching Lab (Room 166).....	Mr David Thompson..... 6933 2123
	Anatomy Teaching Lab (Room 181)	“ “ “ “
Agronomy Research Lab (Bldg 285)	Room 101	Dr Farzad Jahromi 6933 4208
	Room 105	“ “ “ “
Plant Pathology Res Lab (Bldg 280)	Room 110	Dr John Harper..... 6933 2837
	Room 112	“ “ “ “
Animal Science Laboratory (Bldg 280).....	Room 101	Prof Martin Sillence 6933 2205
School of Agriculture	High Security Lab 1	“ “ “ “
	High Security Lab 2	“ “ “ “
	Glasshouse A (Bldg 266).....	Mr David Thompson..... 6933 2123
	Glasshouse B (Bldg 282)	“ “ “ “
	Glasshouse C (Bldg 283)	“ “ “ “
	Hoophouse 1	“ “ “ “
	Hoophouse 2	“ “ “ “
	Hoophouse 3	“ “ “ “
	Animal House	“ “ “ “
	Propagation House	Mr Warwick Grant..... 6933 4002

Notes:

1. PC2 Microbiological only

Appendix 9: Further references

1. Australian National University (ANU) Occupational Health and Safety Unit, *The Australian National University Biological Safety Manual*, ANU, Canberra (2002).
2. Commonwealth of Australia, *The Gene Technology Act 2000*.
3. Commonwealth of Australia, *The Gene Technology Regulations 2001*.
4. Haski, R. *CCH Laboratory Safety Manual*, CCH Australia Limited (2001).
5. National Health and Medical Research Council (NHMRC), *Infection Control in Health Care Settings: Guidelines for the Transmission of Infectious Diseases*, Ausinfo, Canberra (1996). [Note: This publication is currently under review; new edition due late December 2002].
6. New South Wales (NSW) Health Department, *Circular Number 2002/97: Occupational Screening and Vaccination Against Infectious Diseases* (2002).
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Appendix 10: Protocol for granting an exemption to the requirements of the Human Biological Specimens Policy

This protocol should be followed when applying for an exemption to the Human Biological Specimens Policy.

Applications for an exemption may be received at any time, and will be either considered at the next scheduled meeting of the Committee or circulated to all members for a decision by referendum.

Applications for an exemption shall be forwarded to the Executive Officer of the Committee, via the Head of School, with a copy to the appropriate Facility Manager. Heads of School shall endorse the application prior to forwarding it to the Committee. Facility Managers shall have the right to submit comments on each application directly to the Committee.

The following information shall be provided in each application:

- the title of the activity (including whether it is teaching or research);
- scope of the activity;
- type of sample required;
- facility in which the activity will be undertaken; and
- a justification for the exemption (i.e. **why** is it necessary?);

A detailed Risk Management Assessment should accompany each application (including copies of all relevant protocols).

Copies of any other approvals from research-related committees (for example, the Ethics in Human Research Committee) **must** accompany the application.

Applicants must provide sufficient information to enable the Committee to make an informed decision.

If the applicant is applying for an ongoing exemption (for example, for some undergraduate practical classes), they shall nominate the time period (session times) for such exemptions (for a maximum of three years). The period for such exemptions shall be granted on a case-by-case basis. Any change to the protocols in an approved application would necessitate a new application, and all approvals would need to be re-submitted to the Committee after three years;

Heads of School, Facility Managers and applicants shall be notified in writing of the Committee's decision.