Flinders University	Standard Operating Procedure **Disposal of Genetically Modified Organisms, Risk Group 2 Microorganisms & Biohazardous Waste**		
	SOP Number:	**SOP prepared by:**	**Date created:**
	IBC_SOP_6	Jess Hall	August 2016
	IBC approval date:	**Contact:**	**Review date:**
	10/08/2016	ibcadmin@flinders.edu.au	August 2021

1. Relevant Legislation and Policies

- *Gene Technology Act 2000*
- *Gene Technology Regulations 2011*
- *OGTR Guidelines for the Transport, Storage and Disposal of GMOs*
- *Commonwealth Quarantine Act 1908*
- *AS/NZS 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Safety and Containment*
- *Environment Protection Act 1993*
- *Environmental Protection Authority (EPA) Guidelines for Medical Waste – Storage, Transport and Disposal*
- *Flinders University Policy on Research Practice 2001*

2. Biosafety Policy

- Flinders University is accredited by the Office of the Gene Technology Regulator (OGTR) under Section 92 of the *Gene Technology Act 2000* (the *Act*). Any person wishing to undertake work involving risk group 2 (or higher) microorganisms, gene technology and/or Genetically Modified Organisms (GMOs) at the University must seek and receive approval from the Flinders University Institutional Biosafety Committee (IBC) before commencing work. All work involving GMOs must be conducted in accordance with the *Act*, the *Gene Technology Regulations 2011* (the *Regulations*) and associated guidelines. Application forms can be found on the Flinders University biosafety website: http://www.flinders.edu.au/research/researcher-support/ebi/biosafety/resources/forms.cfm
- All staff and students involved in research with GMOs or risk group 2 microorganisms must attend Biosafety Training Day once every three years, or when the *Gene Technology Act* and *Regulations* are updated.

3. Risk Management

Refer to Risk Assessments (RA), Safe Work Method Statements (SWMS) and Safety Data Sheets (SDS) for substances, processes and plant equipment where appropriate. All Notifiable Low Risk Dealings (NLRDs) and work involving risk group 2 (or higher) microorganisms must have an accompanying risk assessment approved by the Institutional Biosafety Committee.

4. Before Work Commences

a) Ensure that you have approval for all decontamination and disposal methods as part of your approved IBC project (see section 5 for further information about prohibited decontamination procedures).

b) RA, SWMS and SDS – ensure you have read and understood for all substances, processes and plant equipment being used.

c) Ensure that you are aware of the locations of the following in the work area(s):
- Spill kit
- Eye wash and safety shower
- Exits
- Required PPE
- Unintentional release flowchart (in Physical Containment facilities)

5. Prohibited Decontamination Procedures

Decontamination of GMOs or risk group 2 microorganisms must not be performed using:
- decontamination equipment that is defective;
- any heat based decontamination equipment for which the results of each month's monitoring tests for the previous 12 months and the results of each year's calibration are not available;
- chemical decontamination agents that are past their expiry date; and
- any method that has not been validated as effective for decontamination of the GMOs or risk group 2 microorganisms.

6. Requirements for the Decontamination and Disposal of GMOs

The following requirements apply to the decontamination or disposal of waste containing GMOs or risk group 2 (RG2) microorganisms, and the decontamination of equipment used in procedures with GMOs or RG2 microorganisms.

Decontamination requirements:

- **Waste containing GMOs from exempt or NLRD PC1 dealings** must be rendered non-viable via autoclaving, disinfection or irreversible fixation prior to disposal, unless the method of disposal is also a method of decontamination (e.g. incineration).
- **Waste containing RG2 microorganisms and GMOs derived from NLRD PC2 dealings** must always be decontaminated via autoclaving or disinfection prior to disposal.
- Researchers who hold an OGTR **licenced dealing (DIR or DNIR)** should follow all decontamination and disposal conditions specified under the licence conditions.
- **Quarantine waste material** must be autoclaved on-site and treated as per requirements specified for the Quarantine Approved Premise (QAP). Please refer to local information in each QAP facility.
- **Equipment** used in procedures with GMOs or RG2 microorganisms must be decontaminated prior to being disposed of or removed from a PC facility.

Decontamination methods and conditions:

- Appropriate decontamination methods depend on the type of waste being treated. Please refer to Appendix A (p. 5) for methods appropriate for different types of waste.

Autoclaving conditions

- Autoclaving is considered the most reliable means of decontamination, but must be conducted using a combination of temperature and time validated as effective for the decontamination of GMOs and RG2 microorganisms:
  - 15 minute (minimum) at 121°C and 103 kPa; or

    - 3 minute (minimum) at 134°C and 203 kPa.
- Any autoclave used must be tested monthly for decontamination efficiency (if you are using an in-built autoclave in the Animal Facility or the Biological Sciences building, routine testing is performed by facility personnel). Results of all monitoring tests must be kept for 12 months and must be made available to the IBC or OGTR upon request. The following monitoring methods may be used:
    - thermocouples or resistance thermometers, to ensure that the required temperature has been reached;
    - chemical indicators which use a combination of moisture, heat and time and which progressively change colour with the time exposed at the specified temperature;
    - biological indicators such as spore strips; or
    - enzymatic indicators.
- Only an autoclave which has been calibrated by a NATA accredited party in the last 12 months can be used. The results of all calibration tests must be kept for a period of 5 years, and be made available to the IBC or OGTR upon request.

<u>Incineration</u>

- At any Flinders facility, all waste disposed of via the biohazard (yellow) waste stream is sent for off-site incineration by an approved contractor.
- Incineration may be used as both the decontamination and disposal method for most biohazard waste (excluding lentiviral waste, and waste containing or derived from NLRD PC2 or RG2 microbiological dealings).

<u>Chemical disinfection</u>

- Chemical disinfection should be used where autoclaving is not possible (e.g. for large surface areas, or for heat-labile materials or equipment).
- Microorganisms vary in their susceptibility to chemical disinfectants. Appendix F of AS/NZS 2243.3:2010 outlines the types of chemical disinfectants suitable for different applications.
- The effectiveness of disinfectants is affected by a range of chemical and physical factors (e.g. concentration, contact time, pH, temperature, inactivation by organic matter). These factors need to be considered when choosing optimal methods and disinfectants for use. Refer to Appendix F of AS/NZS 2243.3:2010 for relevant information relating to individual disinfectants.
- Disinfectants must be clearly labelled with the date of expiry, disinfectant concentration and formulation.

Disposal via biohazardous waste stream (yellow biohazard mobile bins):

- All biohazardous waste must be placed in a yellow biohazard waste bag or sharps container (for contaminated sharps) that is then sealed and placed in a yellow biohazard bin (see Figure 1, p. 4). Double-bagging is recommended.
- The biohazard waste bag must be clearly labelled with the biohazard symbol.
- The lid on the bin must be closable – if the bin is full, please arrange for waste to be collected.
- Yellow biohazard bins are taken by the waste contractor for off-site incineration.

Figure 1: Yellow biohazard bin

Unintentional Release:
In the event of an unintentional release, spill, leak or loss of RG2 microorganisms or GMOs during decontamination or disposal:

- Within Flinders University, refer to the spill or unintentional release flowchart available within each PC facility on campus, and also from the Biosafety website: http://www.flinders.edu.au/research/researcher-support/ebi/biosafety/resources/forms.cfm
- Any real or suspected unintentional release of GMOs outside of a certified PC facility must be reported to the IBC Chairperson (Pam Sykes - ph. 0408722674) or IBC Executive Officer (Jess Hall - ph. 72218353) as soon as reasonably practicable.

7. Contacts, Definitions and References

Contacts:

Position	Name	Contact details
IBC Executive Officer	Jess Hall	ibcadmin@flinders.edu.au ph. 72218353
IBC Chair	Prof Melissa Brown	melissa.brown@flinders.edu.au ph. 82012747

Definitions:

- AS/NZS – Australian/New Zealand Standard
- DIR – Dealing involving Intentional Release
- DNIR - Dealing Not involving Intentional Release
- EPA – Environmental Protection Authority
- GM/GMO – Genetically modified / genetically modified organisms
- IBC – Institutional Biosafety Committee
- NLRD – Notifiable Low Risk Dealing
- OGTR – Office of the Gene Technology Regulator
- PC1/PC2 – Physical Containment level 1 / 2
- PPE – Personal protective equipment
- QAP – Quarantine Approved Premise
- RA – Risk assessment
- RG2 – Risk group 2
- SDS – Safety data sheets
- Animal Facility – College of Medicine and Public Health Animal Facility
- SWMS – Safe work method statement
- SOP – Standard Operating Procedure

References:

- *Australian/New Zealand Standard 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Safety and Containment* **:** https://www.saiglobal.com/online/autologin.asp
    - For a list of appropriate disinfectants, please refer to Appendix F of this Standard
- *Guidelines for the Transport, Storage and Disposal of GMOs*: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/tsd-guidelines-toc
- *Flinders University Biosafety Manual* (March 2015): http://www.flinders.edu.au/about_research_files/Documents/ebi/ibc/Biosafety%20Manual.pdf

8. SOP Review

This SOP currently applies to the disposal of GMOs and RG2 microorganisms from dealings approved by the Flinders University Institutional Biosafety Committee. This SOP will be reviewed every 5 years, but will also be updated more frequently as policies, procedures and requirements change.

Appendix A – Methods of decontamination and disposal for different types of waste

Waste Type	Example(s)	Decontamination method(s)	Disposal method(s)	Notes
General waste	Paper towel from hand-washing, paper waste.	No decontamination required	Place waste in general waste bin (white or black bin bag)	Sharps or glass cannot be placed in the general waste bin. Waste that has been in contact with GMOs, hazardous or infectious materials cannot be placed in the general waste bin.
GMO waste derived from NLRD PC1 and exempt dealings	Tissue derived from a PC1 knock-out animal that has not been infected with PC2 GMO or RG2 microorganisms.	Onsite decontamination is not required for solid waste provided that waste is disposed of via the biohazard (yellow) waste stream. Liquid waste that cannot be disposed of in sealed disposable tubes should be decontaminated prior to disposal. Autoclaving or chemical disinfection is permitted. Follow autoclave procedures in local area, or disinfection methods approved in IBC application.	Double-bag all waste in yellow biohazard waste bags and place in the yellow biohazard bin for off-site incineration. Biohazard bags containing PC1 animal carcasses or tissue should be placed in the chest freezer in the Animal Facility. Animal Facility staff will transfer the bags to the biohazard mobile bins on collection day.	Contaminated sharps or glass cannot be placed into biohazard waste bags. Please use a sharps container.
Liquid RG2 microorganism or NLRD PC2 GMO waste	Broth culture of RG2 or PC2 GM microorganism.	**Onsite decontamination is required prior to disposal.** Decontamination by either autoclaving or chemical treatment is permitted. Follow autoclave procedures in local area, or disinfection methods approved in IBC application.	Following decontamination by autoclaving or chemical treatment, liquid waste can be disposed of via the sewer system.	

Waste Type	Example(s)	Decontamination method(s)	Disposal method(s)	Notes
Solid RG2 microorganism or NLRD PC2 GMO waste	Plate cultures, small volume cultures contained in sealed Eppendorf tubes	**Onsite decontamination is required prior to disposal.** Decontamination by either autoclaving or chemical treatment is permitted. Follow autoclave procedures in local area, or disinfection methods approved in IBC application.	Following decontamination, place bagged waste into the yellow biohazard bin for off-site incineration.	Contaminated sharps or glass cannot be placed into biohazard waste bags. Please use a sharps container.
GM plant material	Tissue from a GM plant or a non-GM plant infected with a GM microorganism; soil or other growth media in which a GM plant was grown	**Onsite decontamination by autoclaving required before disposal.** Follow autoclave procedures in local area.	Following decontamination, waste can be disposed of via the yellow (biohazard) waste stream.	In some facilities, water runoff from GM plants must be captured and decontaminated by chemical disinfection or autoclaving. Follow directions in local area.
Carcasses from RG2 or PC2 GMO infected animals	Includes carcasses from animals infected with either RG2 or GM microorganisms.	**Onsite decontamination by autoclaving required before disposal.** Coordinate autoclaving with Animal Facility staff.	Following decontamination, place carcasses in a biohazard (yellow) waste bag, and place the bag in the chest freezer in the Animal Facility. Animal Facility staff will dispose of carcasses via the biohazard (yellow) waste stream for off-site incineration.	
Biohazard / medical waste	Blood samples, used syringes	Onsite decontamination is not required prior to disposal.	Double-bag all non-sharps waste in yellow biohazard waste bags. Sharps or glass should be disposed of in a yellow sharps container. Dispose of waste into a yellow biohazard bin for off-site incineration.	

Waste Type	Example(s)	Decontamination method(s)	Disposal method(s)	Notes
Quarantine waste	Includes all waste, except general waste, that is generated in a certified Quarantine Approved Premise (QAP).	**All waste must be autoclaved on-site prior to disposal.** Follow all directions specified on relevant import permits and procedures outlined in documentation held within the specific QAP.	Following autoclaving, follow all directions specified on relevant import permits and procedures outlined in documentation held within the specific QAP.	
Reusable lab-ware used with infectious or GM organisms	Flasks, Schott bottles, glass pipettes, secondary containers used during transport of GM or RG2 microorganisms.	Decontaminate glassware by autoclaving. Follow autoclave instructions in your local area. Plastic-ware can be decontaminated using an approved disinfectant.	n/a	
Contaminated sharps	Syringes, broken glass, microscope slides		Contaminated sharps must be disposed of in appropriate biohazard (yellow) sharps containers, which are constructed of rigid plastic resistant to perforation. Full sharps containers should be sealed and disposed of in yellow biohazard bins for off-site incineration.	

Waste Type	Example(s)	Decontamination method(s)	Disposal method(s)	Notes
Lentiviral waste		**All waste must be autoclaved on-site prior to disposal.** Liquid lentiviral waste must be treated with 1% Virkon solution or by autoclaving prior to disposal. Solid waste that has been in contact with, or contains, lentivirus must be autoclaved on-site prior to disposal. Place waste in doubled yellow bags in a metal receptacle (e.g. metal bucket) and coordinate with the Animal Facility staff to arrange autoclaving. ***SEE NOTES***	Following decontamination, liquid waste can be disposed of via the sewer system. Solid waste can be placed in yellow biohazard bins for off-site incineration.	If waste has been treated with bleach, do not autoclave. *Refer to **Recombinant Adenovirus & Lentivirus Safety SWMS** for specific methods & instructions for decontamination, available at: https://www.flinders.edu.au/mnhs/staff/safety-facilities-unit/risk-assessment-and-safe-work-method-statements.cfm