

Appendix 11

Approved User – Internal Audit Form

University of Otago, Wellington – Containment and Transitional Facilities

Vertebrate Laboratory Animals, Microorganisms, Cell Cultures and Uncleared Biologicals

(Please cross out the designation that does not apply here and throughout the document)

Name/Approved User: _____

Date: _____

Section 1

All Approved Users must fill out Section 1 and other sections that are relevant

		Yes	No	N/A
1.	I am listed as an Approved User in the Quality (Containment and Transitional) Manual for the University of Otago, Wellington Campus			
2.	I have received training covering, and am familiar with, the operating requirements of the Facility including the requirements of MAF Biosecurity Authority Standards 154.03.3, Facilities for Microorganisms and Cell Cultures: 2007a and MPI Standard 154.02.17, amended 14 February 2014			
3.	I have attended at least one refresher seminar on Facility requirements within the last 12 months			
4.	The Laboratory Compliance Officer holds records of my training			
5.	I am familiar with the contents of the Quality (Containment and Transitional) Manual for the Facility(s) in which I work, and all the documented details for the Sector in which I work are correct. If they are not correct, note the changes on page 2			
6.	I am familiar with the required PC2 Containment conditions as defined in AS/NZS2243.3, and all my work complies with the appropriate operating procedures			
7.	PC2 operating procedures are displayed in the Facility			
8.	SUPERVISORS: All people that work in the Facility under my supervision have received appropriate training for the handling of laboratory animals, microorganisms and/or uncleared biologicals, and are familiar with the operating requirements of the Facility			

9.	SUPERVISORS: All training of people under my supervision has been documented and the documentation is available for inspection			
10.	I have approval from EPA or the IBSC (as appropriate) for all transgenic animal lines and/or genetically modified organisms (including cell cultures) that I work with			
11.	The Laboratory Compliance Officer has a copy of all relevant EPA/IBSC approvals and controls			
12.	A BACC accompanies all imports into the Facility (or is obtained as soon as possible)			
13.	There is a prominent sign designating "Restricted Access: no unauthorised entry" displayed at all entrances to restricted areas			
14.	A sign detailing how unauthorised persons may gain access is posted at public entrances			
15.	Sector doors are kept locked when the laboratory is unattended			

If "NO" has been answered to any of the above, please asterisk item and indicate what corrective actions are being taken and when the corrective actions will have been completed. (If corrective action is not required, please explain).

Signed: _____ Date: _____
 (Approved User)

Section 2

To be filled in by those who work with uncleared biologicals

		Yes	No	N/A
1.	I know what an uncleared biological is			
2.	A form has been filled in for each uncleared biological imported into the Facility and is filed with the associated paperwork			
3.	The register of uncleared biologicals is up to date			
4.	When an uncleared biological is destroyed all audit forms are updated with appropriate dates and methods			
5.	All Biosecurity Authority Clearance Certificates (BACCs) have been filed with the audit forms			
6.	All audit forms for uncleared biologicals that have been destroyed have been updated with the date they have been destroyed			

If "NO" has been answered to any of the above, please asterisk item and indicate what corrective actions are being taken and when the corrective actions will have been completed. (If corrective action is not required, please explain).

Signed: _____ Date: _____
(Approved User)

Section 3

To be filled in by those who work with microorganisms and cell cultures

		Yes	No	N/A
1.	My work involves microorganisms that are new organisms but are not genetically modified organisms			
2.	My work involves the use of genetically modified organisms/cell cultures			
	If you have answered NO to both questions, continue from Q.6. If you have answered YES to either or both questions complete below:			
3.	All work involving GMO development or importation has received approval under the HSNO legislation. Please list all your approvals below and if they are active/inactive			
4.	I am the leader of a project			
	If yes to the above, a register for genetically modified microorganisms (including cell cultures) has been completed and filed with the Sector Manager for all projects			
5.	I am the curator of a culture collection			
	If yes to the above, an up-to-date register of culture collections showing all importations and transfers is available for inspection			
6.	My work involves cell cultures (animal)			
7.	If yes to the above, a register is maintained and updated regularly			
8.	A copy of the Import Health Standard/Biosecurity Authority Clearance Certificate (BACC) has been attached to the record where appropriate			

If "NO" has been answered to any of the above, please asterisk item and indicate what corrective actions are being taken and when the corrective actions will have been completed. (If corrective action is not required, please explain).

Signed: _____ Date: _____
(Approved User)

Section 4

To be filled in by those who work with vertebrate laboratory animals

		Yes	No	N/A
1.	I am familiar with the register of laboratory animals which is updated on a monthly basis			
2.	My work involves the exposure of laboratory animals to uncleared biologicals or microorganisms			
	If yes to the above, I am familiar with the requirements "Exposure of Experimental Animals to Restricted Biological Products" specified in Appendix 11 of the Quality (Containment & Transitional) Manual (February 2017 version 1.5)			
3.	All work with animals in the area in which I work has Animal Ethics Committee approval			
4.	I am familiar with the requirements for the temporary (48 hours) removal of laboratory animals from the Facility and the movements are recorded in the register			
5.	I am familiar with the requirements for the transfer of laboratory animals from one Containment Facility to another			

If "NO" has been answered to any of the above, please asterisk item and indicate what corrective actions are being taken and when the corrective actions will have been completed. (If corrective action is not required, please explain).

Signed: _____ Date: _____
(Approved User)

Declaration Page

I hereby confirm that corrective actions:

(Circle applicable phrase and delete non-applicable phrase)

1. Were not required.

2. Were required.

Signed: _____ Date: _____
(Approved User)

Please pass this form on to the Sector Manager