



	CERMEL- REPORT/ CORRECTIVE ACTION PLAN/ INTERNAL AUDIT		
Department	CERMEL / Nagasaki University joint research laboratory BSL2/3		
Lab Visit Date	14 December 2018		
Auditor	Thierry GANZI, Hutch-L'herbier NZENGUELE		

Status definitions:	C = Critical finding	M = Major finding	O = "Other"
	A critical finding is a deviation compromising a study conduct and when the validity/ integrity of the data are affected. This deviation may require that further operations stop until corrective action is complete.	Major finding is a deviation relative to the principles of Good Clinical Laboratory Practice (GCLP) or to study procedure or other Standard Operating Procedures (SOPs) applicable to the audited activity. This deviation is either major or frequent or has an important impact on the activity. Corrective action is requested to be completed at the latest 6 weeks after receiving this report or at an indicated due date.	"Other" is a deviation relative to the principles of Good Clinical Laboratory Practice (GCLP) or to study procedures or other Standard Operating Procedures (SOPs) applicable to the audited activity. This deviation has an indirect impact on the activity or is considered less significant than "Major". Corrective action related to each "Other" finding is requested to be completed within a time agreed by Lead auditee/ or responsible person and auditor.

INSTRUCTIONS:
 Please insert your corrective action response to each finding in column D as well as the responsible person in column E and due date for resolution in column F. **NOTE:** Due date can be already given by the auditor.
 The status can be updated in column G, i.e., either the corrective action is pending or completed at the time of submission of the corrective action template back to the auditor.

Hutch-L'herbier Nzenguele

biological safety						
1. Laboratory						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
1.1.	No adequate marking: - Pictogram of biological danger on all rooms, appliances, autoclaves, centrifuges ...	O	Stick pictograms of biological danger, electrical and chemical Hazards on the devices requiring it	Hutch	01/08/2018	C
1.2.	No copy of biosecurity manual on site Hand hygiene guidelines are not displayed.	O	Get in touch with Rodrigue, to obtain a copy of the biosecurity manual	Yuri	15/09/2018	C
1.3.	Refer to 1.1	O	See 1.1	Hutch	01/08/2018	C

2. Laboratory design

A	B	C	D	E	/F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
2.4.	Congestion: - Presence of devices on traffic lanes, - Laboratory equipment on laboratory instruments	O	Move the devices from the crossing paths Install shelves to avoid dropping of some equipment on other devices	Yuri Abe	15/09/2018	C

3. Chemical

A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
3.1.	Limited quantity of chemicals (ex: Bleach, EtOH): - No stock - Provide secure cabinet for storage of large quantities of chemicals	M	No large quantities of products stored in the laboratory. However, setting up a cabinet for small quantities of products	Yuri Abe	15/09/2018	C

3.6.	Solution Labelling: - Absence of initial, date of preparation and expiration on the vial of bleach	M	Identification of all lab preparations	Yuri Abe	15/09/2018	C
------	--	---	--	----------	------------	---

4. Refrigerators, freezers, cold rooms						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
4.1.	- No food in the laboratory but no note or pictograms forbidding the storage of food in refrigerators	O	Paste on electronic devices (fridge, freezers) as well as on doors pictograms and notes forbidding to eat in the lab or put drink in the fridge or freezer	Yuri Abe	15/09/2018	C

5. Electrical equipment						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)

5.1.	- Extension cords running through traffic lanes, risk of accidents	M	Remove the extension cords from the floor (pathways and fix them to the wall and ceiling)	Yuri Abe Arnold	05/08/2018	C
------	--	---	---	-----------------	------------	---

6. individual protection equipment						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
6.1	- No eye rinses in the laboratory	M	Ask Dr Josiane for an eyewash and hand over to Yuri or Abe. Also constitute a biological spill kit	hutck	25/08/2018	C
6.4.	- PPE not worn out of the laboratory but no note meaning	O	Write and post a note and if possible, a pictogram prohibiting the wearing of PPE outside the laboratory	Hutch	05/09/2018	C

7. Waste management						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)

7.2.	Sorting of waste: - Non-existent for infectious waste	M	Identify the trash cans, stick the waste disposal sheet and hand over the sop " management of biomedical waste "	Hutch	03/08/2018	C
7.3.	Chemical waste container: - Not available	M	Put at disposal of the laboratory containers for sharps items	Yuri Abe	15/07/2018	C
7.5.	Container for sharp objects, sharp, sharp: - Not available	M	Paste posters on waste disposal	Hutch	15/07/2018	C
7.7.	Procedure for the disposal of waste: - Not available	M		Hutch	15/07/2018	C

8. Existence of occupational health and safety programs						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
8.1.	Risk Communication: - Copy of biological safety manual not available in the laboratory.	M	Refer to 1.2	Rodrigue	15/09/2018	C
8.2.	- Refer to 8.1.	O		Rodrigue		C

9. Technical control systems						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
9.2.	Waste disposal in Wash basin: - Lack of note indicating the type of waste to be disposed of in the sink	M	Translate, implement and paste waste disposal circuit boards	Hutch	15/07/2018	C
9.3.	Arthropod and rodent control program: - Non-existence of the control program	M	Write a procedure against arthropods and rodents	Hutch	10/08/2018	P

10. Practices and general rules						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
10.1.	- No note or pictograms forbidding eating, drinking in the	M	Write and stick a note to forbid drinking and eating even consume ice from the ice churn out.	Yuri Abe	15/09/2018	C

10.3.	<ul style="list-style-type: none"> - laboratory or consuming ice from the ice machine - No note prohibiting mouth pipetting 	O	To establish	Yuri Abe	15/09/2018	P
-------	---	---	--------------	----------	------------	---

11. General holding of the laboratory						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
11.2.	Risk of tripping: <ul style="list-style-type: none"> - Electrical cables crossing the passageways 	M	Refer to 5.1	Yuri Abe	15/09/2018	C

12. Fire safety						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
12.1.	<ul style="list-style-type: none"> - Restricted circulation areas 	O	No solution at the moment. Built like that	Yuri Abe	15/09/2018	P

1. Microbiological safety station (MSS)

A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
1.4.	- Naked flames used in the enclosure of the PSM, in deflection with the norm in force and SOP in CERMEEL	M	Hood adapted to the use of naked flames.	Yuri Abe	15/09/2018	C

2. Laboratory

A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
2.2.	- No biological hazard sign posted on the laboratory door	M	Stick biohazard pictograms on doors.	Yuri Abe	15/09/2018	C
2.3.	- The doors are not constantly closed	M	Activate the automatic door closing system	Yuri Abe	15/09/2018	C

3. Decontamination

A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
3.2.	Infectious material prevalent or involved in an accident: - No documentation proving that the head of the laboratory should be informed	M	Get inspired by the research laboratory biosafety manual	Rodrigue		P

4. Handling of contaminated waste

A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
4.1.	Container use of contaminated waste: - Autoclaved waste but no bins available for biomedical waste	M	Order bins from the administration	Hutch	10/08/2018	C

5. Individual protection						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)

6. Practices						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)

7. Commodities						
A	B	C	D	E	F	G

Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
7.1.	- Washbasins not installed near the exit	O	Not taken into account during the construction of the laboratory	Yuri Abe	15/09/2018	P

Containment Laboratory -BSL3: Security Control

1. Laboratory design						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
1.2.	Automatic closing of the vestibule: - Non-operational system on the day of the audit	M	Activate the vestibule closing system	Yuri Abe	15/09/2018	C
1.4.	Local Air: - Non-operational ventilation system on the day of the audit	M	Activate the local air system	Yuri Abe	15/09/2018	C
1.5	Ventilation system: - Non-operational ventilation system on the day of the audit	M	Activate the ventilation system	Yuri Abe	15/09/2018	C

3. individual Protection						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
3.2	No display prohibiting the wearing of Lab coat outside the laboratory	M	Write and paste the note forbidding the wearing of Lab coat out of the laboratory	Yuri Abe	15/09/2018	C
3.3	No washbasin operated by foot or automatic trigger:	M	In thought	Yuri Abe	15/09/2018	P

6. Practices						
A	B	C	D	E	F	G
Section of the Assessment Checklist	Auditors Finding/ Recommendation	Status of finding	Lab's Response	Responsible Person	Due date	Status (Pending/Complete)
6.1.	Risks related to pathogens: - Manual not available - No display	M	collect a copy of a situational analysis by Hutch	Yuri Abe	15/09/2018	C

L-G-032-T7-V02-EN: Report- Corrective Action Template

6.2.	Staff training schedule: - No documentation to this effect	M	refer to 10.3	Yuri Abe	15/09/2018	P
6.3.	Autoclaving waste: - No autoclave available in the room	M	Install an autoclave in the laboratory	Yuri Abe	15/09/2018	C