



| | CERMEL- REPORT/ CO | CERMEL- REPORT/ CORRECTIVE ACTION PLAN/ INTERNAL AUDIT | VAL AUDIT |
|---------------------|---|--|--|
| Department | CERMEL / Nagasaki University joint research laboratory BSL2/3 | niversity ory BSL2/3 | |
| Lab Visit Date | 14 December 2018 | | |
| Auditor | Thierry GANZI, Hutch-L'herbier NZENGUELE | herbier NZENGUELE | |
| Status definitions: | C = Critical finding | M = Major finding | O = "Other" |
| | A critical finding is a | Major finding is a deviation relative | "Other" is a deviation relative to the principles of |
| | deviation | to the principles of Good Clinical | Good Clinical Laboratory Practice (GCLP) or to |
| | compromising a study | Laboratory Practice (GCLP) or to | study procedures or other Standard Operating |
| | conduct and when | study procedure or other Standard | Procedures (SOPs) applicable to the audited |
| | the validity/ integrity of | Operating Procedures (SOPs) | activity. |
| | the data are | applicable to the audited activity. | This deviation has an indirect impact on the |
| | affected. | This deviation is either major or | activity or is considered less significant than |
| | This deviation may | frequent or has an important impact | "Major". |
| | require that further | on the activity. | Corrective action related to each "Other" finding |
| | operations stop until | Corrective action is requested to be | is requested to be completed within a time |
| | corrective action is | completed at the latest 6 weeks | agreed by Lead auditee/ or responsible person |
| | complete. | after receiving this report or at an | and auditor. |
| | | indicated due date. | |
| INICATE ICATIONS. | | | |

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-Cherner Houguele

L-G-032-T7-V02-EN: Report- Corrective Action Template Basic Laboratory -BSL1: Security control

| 1.3. | 1.2 | Section of the Assessment Checklist | A | | |
|--------------|---|-------------------------------------|---|---------------|-------------------|
| Refer to 1.1 | No adequate marking: - Pictogram of biological danger on all rooms, appliances, autoclaves, centrifuges No copy of biosecurity manual on site Hand hygiene guidelines are not displayed. | Auditors Finding/ Recommendation | 8 | | |
| 0 | 0 0 | Status of finding | С | | D |
| See 1.1 | Stick pictograms of biological danger, electrical and chemical Hazards on the devices requiring it Get in touch with Rodrigue, to obtain a copy of the biosecurity manual | Lab's Response | D | 1. Laboratory | biological safety |
| Hutch | Yuri Hutch | Responsible Person | Е | | |
| 01/08/2018 | 01/08/2018 | Due date | П | | |
| O | ი ი | Status (Pending/Complete) | G | | |



| | | | 2. Laboratory design | | | |
|---|---|----------------------|--|-----------------------|------------|------------------------------|
| A | | C | D | т | /F | G |
| Section of the Auditors Finding/ Assessment Recommendation | | Status of finding | Lab's Response | Responsible Person | Due date | Status (Pending/Complete) |
| 2.4. Congestion: - Presence of devices on tra lanes, - Laboratory equipment on laboratory instruments | ce of s on traffic tory lent on ory lents | 0 | Move the devices from the crossing paths the crossing paths Install shelves to avoid dropping of some equipment on other devices | Yuri Abe | 15/09/2018 | ი ი |

| 3.7 .7 | Section of the Assessment Checklist | А | |
|--|-------------------------------------|---|-------------|
| Limited quantity of chemicals (ex: Bleach, EtOH): - No stock - Provide secure cabinet for storage of large quantities of chemicals | Auditors Finding/ Recommendation | В | |
| Σ. | Status of finding | C | Angal. |
| No large quantities of products stored in the laboratory. However, setting up a cabinet for small quantities of products | Lab's Response | D | 3. Chemical |
| Yuri Abe | Responsible Person | т | |
| 15/09/2018 | Due date | п | |
| n | Status (Pending/Complete) | G | |



| 4 .1. | Section of the Assessment Checklist | A | | ა. ნ |
|---|-------------------------------------|---|-------------------------------------|--|
| No food in the laboratory but no note or pictograms forbidding the storage of food in refrigerators | Auditors Finding/ Recommendation | В | . | Solution Labelling: - Absence of initial, date of preparation and expiration on the vial of bleach |
| 0 | Status of finding | C | | Z |
| 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 | Lab's Response | D | Refrigerators, freezers, cold rooms | Identification of all lab preparations |
| Yuri Abe | Responsible Person | т | oms | Yuri Abe |
| 15/09/2018 | Due date | п | | 15/09/2018 |
| O | Status (Pending/Complete) | G | | O |

| Section of the Assessment Checklist | A | |
|---|---|----------------------|
| Auditors Finding/ Recommendation | B | |
| Status of finding | C | |
| Lab's Response | ס | Electrical equipment |
| Responsible Person | П | |
| Duedate | п | |
| Status (Pending/Complete) | G | |

| - Extension cords running through traffic lanes, risk accidents | | | 5.1. | L-G-032-T7-V02-EN: Report- Corrective Action T |
|---|-----------|-----------------|---------------------|--|
| i Template M h sk of | accidents | running through | - Extension cords M | ort- Corrective Action Template |

| = | _ | | 0 | —— TI | |
|----------------------|-------------------|----------------|-----------------|------------|--|
| them to the wall and | (pathways and fix | from the floor | extension cords | Remove the | |
| | | ₽ | > | ~ | |

ceiling)

| nold | be | Ľ. |
|------------|----|----|
| 05/08/2018 | | |
| C | | |

| | | 6. indiv | individual protection equipment | ant | | |
|---|--|----------------------|--|-----------------------|------------|------------------------------|
| A | В | C | D | E | F * 1 | G |
| Section of the Assessment Checklist | Auditors Finding/ Recommendation | Status of finding | Lab's Response | Responsible Person | Due date | Status (Pending/Complete) |
| <u>. 7</u> დ | No eye rinses in the laboratory | ٤ | Ask Dr Josiane for an eyewash and hand over to Yuri or Abe. Also constitute a biological spill kit | hutch | 25/08/2018 | ဂ |
| 6.4. | - PPE not worn out O of the laboratory but no note meaning | 0 | Write and post a note and if possible, a pictogram prohibiting the wearing of PPE outside the laboratory | Hutch | 05/09/2018 | 0 |

| Section of the Assessment Checklist | Α | |
|---|---|------------------|
| Auditors Finding/ Recommendation | œ | |
| Status of finding | C | 7. |
| Lab's Response | D | Waste management |
| Responsible Person | п | |
| Due date | F | |
| Status (Pending/Complete) | G | |



| 7.7. | | 7.5. | | | 7.3. | | | | 7.2. | L-G-032-T7-V02-EN: R |
|--|---|------------------|------------------------|----------------|----------|--|---------------------|--------------------------------------|--------------------------|---|
| Procedure for the disposal of waste: - Not available | Container for sharp objects, sharp, sharp: Not available | | container: | Chemical waste | | waste | infectious | Non-existent for | Sorting of waste: | L-G-032-T7-V02-EN: Report- Corrective Action Template |
| 3 | | S | | | S | | | | S | ıplate |
| | Paste posters on waste disposal | for sharps items | Put at disposal of the | | | the sop " management of biomedical waste " | sheet and hand over | stick the waste disposal | Identify the trash cans, | |
| Hutch | | Hutch | | Abe | Yuri | | | | Hutch | |
| 15/07/2018 | 11111 | 15/07/2018 | 7.14 | | | | | | 03/08/2018 | - 1 |
| O | | 0 | | | | | | | ဂ | |

| | 8. Exist | lence of occ | Existence of occupational health and safety programs | fety programs | | |
|---|---|----------------------|--|-----------------------|------------|------------------------------|
| A | œ | C | D | П | П | G |
| Section of the Assessment Checklist | Auditors Finding/ Recommendation | Status of finding | Lab's Response | Responsible Person | Due date | Status (Pending/Complete) |
| 8.7 | Risk Communication: - Copy of biological safety manual not available in the laboratory. | Σ. | Refer to 1.2 | Rodrigue | 15/09/2018 | n |
| 8.2. | - Refer to 8.1. | 0 | | Rodrigue | | O |



| | | 9. | Technical control systems | SWS | | |
|---|---|-------------------|--|-----------------------|------------|------------------------------|
| A | w i | C | D | m | П | 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 | ≤ | Translate, implement and paste waste disposal circuit boards | Hutch | 15/07/2018 | O |
| 9 3 | Arthropod and rodent control program: - Non-existence of the control program | Z | Write a procedure against arthropods and rodents | Hutch | 10/08/2018 | ס |

| | | 10. Pra | 10. Practices and general rules | • | | |
|---|--|----------------------|---|-----------------------|------------|------------------------------|
| Α | В | C | D | | 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 | Σ, | Write and stick a note to forbid drinking and eating even consume ice from the ice churn out. | Yuri Abe | 15/09/2018 | C |

| | | | | | | | | Ţ |
|--------------|---------------------|-------------|-----------|---------|--------------|---------------|---------------|---|
| | 10.3. | | | | | | | -G-032-T7-V02-EN: Repo |
| | mouth pipetting O | prohibiting | - No note | machine | from the ice | consuming ice | laboratory or | L-G-032-T7-V02-EN: Report- Corrective Action Template |
| | 0 | | | | | | | late |
| To establish | | | | | | | | _ |
| | Abe | Yuri | | | | | | |
| | | 15/09/2018 | | | | | | |
| | | ס | | | | | | |
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| | _ | 1. Gener | 11. General holding of the laboratory | tory | | |
|-------------------------------------|--|----------------------|---------------------------------------|-----------------------|------------|------------------------------|
| A | 8 | C | D | т | П | 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: - Electrical cables crossing the passageways | ≤ | Refer to 5.1 | Yuri Abe | 15/09/2018 | ဂ |

| | | | | | areas | |
|------------------------------|------------|-----------------------|-------------------------|----------------------|-------------------------------------|-------------------------------------|
| | | Abe | moment. Built like that | | circulation | |
| <u>"</u> " | 15/09/2018 | Yuri | No solution at the | 0 | Restricted | 12.1. |
| Status (Pending/Complete) | Due date | Responsible Person | Lab's Response | Status of finding | Auditors Finding/ Recommendation | Section of the Assessment Checklist |
| G | п | m | D | C | ₩. | Α |
| | | | 12. Fire safety | 4 | | |

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

Basic Laboratory-BSL2: Security control

| | Office of the control | I. Microbiol | 1. Microbiological safety station (MSS) | 3S) | | |
|---|--|-------------------|--|-----------------------|------------|------------------------------|
| Α | В | C | ם | ш | П | 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 CERMEL | Σ, | Hood adapted to the use of naked flames. | Yuri Abe | 15/09/2018 | C |

| | | | 2. Laboratory | | | |
|-------------------------------------|---|----------------------|--|-----------------------|------------|------------------------------|
| Α | W | C | D | т | 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 | ٤ | Stick biohazard pictograms on doors. | Yuri Abe | 15/09/2018 | ဂ |
| 2.3. | The doors are not constantly closed | 3 | Activate the automatic door closing system | Yuri Abe | 15/09/2018 | C |

| | | မှ | 3. Decontamination | | | |
|-------------------------------------|--|----------------------|--|-----------------------|----------|------------------------------|
| A | B | C | D | т | ח | 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 | S | Get inspired by the research laboratory biosafety manual | Rodrigue | | ים |

| | | 4. Handlin | 4. Handling of contaminated waste | О | | |
|-------------------------------------|--|----------------------|------------------------------------|-----------------------|------------|------------------------------|
| Α | W | C | D | Ш | 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 | Z | Order bins from the administration | Hutch | 10/08/2018 | 0 |



| | S | | |
|---|---|---|--------------------------|
| 5.5. | Section of the Assessment Checklist | Α | |
| Hand hygiene: - No documentation or note to this effect | Auditors Finding/ Recommendation | Œ | |
| 0 | Status of finding | C | 5. In |
| Paste hand hygiene posters | Lab's Response | D | 5. Individual protection |
| Thierry | Responsible Person | Е | |
| 05/08/2018 | Due date | П | |
| С | Status (Pending/Complete) | G | |

| 6.2. | Section of the Assessment Checklist | Α | |
|--------------------------|-------------------------------------|---|--------------|
| No biosecurity manual. M | Auditors Finding/ Recommendation | w | |
| ٤ | Status of finding | ဂ | |
| Refer to 8.1 | Lab's Response | D | 6. Practices |
| Yuri Abe | Responsible Person | т | |
| 15/09/2018 | Due date | п | |
| C | Status (Pending/Complete) | 9 | |

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| די | 15/09/2018 | Yuri Abe | Not taken into account during the construction of the laboratory | 0 | - Washbasins not installed near the exit | <mark>7.1</mark> . |
|-----------------------------|------------|-----------------------|--|-------------------|--|---|
| Status (Pending/Complete | Due date | Responsible Person | Lab's Response | Status of finding | Auditors Finding/ Recommendation | Section of the Assessment Checklist |

Containment laboratory -BSL3: Security Control

| | | <u>-</u> | 1. Laboratory design | | | 98. 5.3 5.3 7.3 8.3 8.3 8.3 8.3 8.3 8.3 8.3 8.3 8.3 8 |
|---|--|----------------------|---------------------------------------|-----------------------|------------|--|
| А | В. | C | D | m | п | 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 | S | Activate the vestibule closing system | Yuri Abe | 15/09/2018 | ೧ |
| | day of the audit | | | Yuri. | 15/09/2018 | O |
| 1.4. | Non- operational | 3 | Activate the local air system | Abe | | |
| | ventilation system on the day of the audit | | | | | |
| 1.5 | Ventilation system: | ≤ | Activate the ventilation | Yuri Abe | 15/09/2018 | C |
| | - Non- | | system | | | |
| | operational ventilation | | | | | |
| | system on the | | | | | |
| | day of the audit | | | | | |



| ω ω | 3.2 | Section of the Assessment Checklist | Α | |
|--|---|---|---|--------------------------|
| No washbasin operated by foot or automatic trigger | No display prohibiting the wearing of Lab coat outside the laboratory | Auditors Finding/ Recommendation | Œ | |
| <u> </u> | Z | Status of finding | C | 3. in |
| In thought | Write and paste the note forbidding the wearing of Lab coat out of the laboratory | Lab's Response | D | 3. individual Protection |
| Yuri Abe | Yuri Abe | Responsible Person | т | |
| 15/09/2018 | 15/09/2018 | Due date | П | |
| ס | C | Status (Pending/Complete) | G | |

| | | | 6. Practices | | | |
|---|---|----------------------|---|-----------------------|------------|------------------------------|
| Þ | W | C | D | П | F | G |
| Section of the Assessment Checklist | Auditors Finding/ Recommendation | Status of finding | Lab's Response | Responsible Person | Due date | Status (Pending/Complete) |
| თ .1 | Risks related to pathogens: - Manual not available - No display | ٤ | collect a copy of a situational analysis by Hutch | Yuri Abe | 15/09/2018 | C |

| —. | -G-032-T7-V02-EN: Rep | L-G-032-T7-V02-EN: Report- Corrective Action Template | plate | | | - (|
|----|-----------------------|--|-------|--|-------------|------------|
| | 6.2. | Staff training schedule: - No documentation to this effect | S | refer to 10.3 | Yuri Abe | 15/09/2018 |
| | თ .ა | Autoclaving waste: - No autoclave available in the | Z | Install an autoclave in the laboratory | Yuri Abe | 15/09/2018 |