Audit on biosafety

Table 1.Basic Laboratory-BSL1

Place: CERMEL Joint Research Laboratory / Nagasaki University	Date: 30 April 2018				
Head of laboratory: Dr Marguerite Massinga Lombe					
Person (s) audited and post: Dr Haruka Abe, Assistant Prof / Dr Yuri Ushijima, Post-doc					
controlled points	**Yes**	**No**	**Partial**	**Means of verification**	**Observations**
1. Laboratory					
1.1. Is signalling appropriate: hazardous substances?		✓		**Visual verification, MSDS and / or implementation cards**	• No adequate marking to know biological hazard pictogram on all rooms, appliances, autoclaves, centrifuges
1.2. Are biosecurity guidelines existing and known?		✓		**Visual Verification (Pictogram), Biosafety Manual (read and signed)**	• No copy of the biosecurity manual on site • Guidelines for hand hygiene are not displayed
1.3. Are laboratory equipment properly marked (biological hazard, radioactivity, toxicity, etc.)?		✓		**Visual verification (Pictogram)**	
Access and good practice code: *The international pictogram of biological hazard must be affixed to the doors of rooms where micro-organisms belonging to risk group 2 or higher groups are handled.* *A biological hazard sign on the laboratory door should indicate the level of biosecurity and the name of the laboratory manager responsible for access to the premises* ***WHO Biosafety Manual, 2010, pages 10 and 22*** ***Biosecurity management:*** *The laboratory must have a copy of the laboratory manual or health and safety guide.* *The staff must be aware of the risks specific to the laboratory's activities and read the manual* ***WHO Biosafety Manual, 2010, page 12***					
2. Laboratory design					
2.1. Are the shelves securely fixed?	✓			**Visual verification**	
2.2. Is bench top coating waterproof and resistant to acids, bases, organic solvents and heat?	✓			**Visual verification**	
Coating of the benches: *Countertop work surfaces must be waterproof, resistant to disinfectants, acids, alkalis and organic solvents and be able to withstand moderate heat.* ***WHO Biosafety Manual, 2010, page 14***					
2.3. Are the rooms adequately lighted?	✓			**Visual verification**	Lighting in each room
Norm: *The laboratory space must be sufficient to ensure the quality of work, the safety of staff and the ability of staff to carry out quality control and documentation procedures. The laboratory must be clean and well organized, free from congestion, well ventilated, well-lit and within acceptable temperature ranges.* ***ISO 15190: 6.3.1***					

2.4. Are storage spaces adequate and properly used?		✓		**Visual verification and related documentation (Reagent storage sheets)**	Congestion: presence of devices on ways, and laboratory equipment on laboratory instruments
Storage spaces: *The storage spaces must be able to receive the current equipment, so as to avoid the bulk of the benches and the passage areas.* ***WHO Biosafety Manual, 2010, page 15***					
3. Chemicals					
3.1. Are flammable products stored in appropriate cabinets?				**Visual verification and related documentation (Reagent storage sheets)**	Limited quantity chemical (eg bleach, EtOH) No stock on site Provide secure cabinet for large quantity storage
3.2. Are the products properly separated?	✓			**Visual verification and related documentation (Reagent storage sheets)**	
3.3. Are dangerous products stored above eye level?		✓		**Visual verification**	
3.4. Are products stowed on the ground?		✓		**Visual verification**	
3.5. Do chemical containers remain open during and after use?		✓		**Visual verification**	
3.6. Are the solutions correctly labelled?			✓	**Visual verification**	Bleach: lack of initials, date of preparation and expiration Missing danger marking
Labelling of chemicals: *All hazardous chemicals must be Labelled with the chemical name and clearly marked hazard markings.* ***ISO 15190: 17.1 et 17.3***					
3.7. Are flammable products stored in secure or explosion proof units?				**Visual verification and related documentation (Reagent storage sheets)**	NA: No stock of chemicals in the lab
Norm: *Flammable chemicals should be stored away from solar radiation and below their flash point, preferably in a well-ventilated area. Flammable and corrosive agents must be separated from each other. Special care must always be taken to manage the safety of hazardous chemicals in the workplace.* ***ISO 15190: 17.1 et 17.3***					
4. Refrigerators, freezers, cold rooms					
4.1. Are foods for human consumption stored in refrigerators and freezers?			✓	**Visual verification**	No food in the laboratory. However, no signage prohibiting the storage of food in refrigerators
Norm: *Personnel foodstuffs must be stored in separate areas reserved for this purpose, and not in the laboratory storage areas, especially in the cold room. Laboratory reagents and blood products should be stored separately when refrigerated or frozen.* ***ISO 15190: 11.1***					
4.2. Are carcinogenic, radioactive or biohazardous substances indicated by an external mark?				**Visual verification (Pictogram)**	NA: Absence of chemicals in the laboratory

Norm:** All hazardous chemicals must be labelled with the chemical name and clearly marked hazard markings.* ***ISO 15190: 17.1 et 17.3					
4.3. Is there a temperature management system?			✓	**Visual verification and documentation (temperature log)**	Presence of thermometers in each room Log of temperature monitoring not systematically informed
Norm:* ISO 15189: 5.2.5 «The laboratory shall monitor, control and record environmental conditions in accordance with the corresponding specifications or where they are likely to influence the quality of the results»*** ***CERMEL SOP: Monitoring temperatures fridges and freezers(L-G-029-V04-EN)***					
4.4. Is there a preventive or annual maintenance of the devices?		✓		**Visual verification and documentation (equipment maintenance log, annual maintenance labels)**	**Note**: No maintenance to date, newly installed laboratory Equipment installation documentation not available in the laboratory
Norm:** Preventive maintenance should be performed by operators on all equipment used for testing, including centrifuges, autoclaves, microscopes and safety cabinets* ***ISO 15189: 4.2.5, 5.3.2 ***CERMEL SOP: General usage and maintenance of microscopy (L-G-027-V06-EN)***					
5. Electrical equipment					
5.1. Are extension cords properly placed in theatres?		✓		**Visual verification**	Many extensions passing crossing areas, high accident risk
5.2. Are there electric cables on the ground?	✓			**Visual verification**	
5.3. Are the wafers connected to the floor?	✓			**Visual verification**	
5.4. Are outlets and other connections near sinks, under showers, etc... ?		✓		**Visual verification**	
5.5. Are plugs or inserts with connections overloaded?		✓		**Visual verification**	
5.6. Do outlets close to water supply comply with local regulations?				**Visual verification**	NA
5.7. Are there device protections against power interruptions and / or overloading?	✓			**Visual verification**	Generator + UPS
Norm:** Cords, plugs, extension cords and electrical outlets must be kept in good condition and used appropriately. Any congestion should be avoided and cords should be kept out of areas of passage.* ***ISO 15190: 19.7 et 9.3					
6. Personal protective equipment					
6.1. Are there eye rinses in the laboratory?		✓		**Visual verification and related documentation (Biosafety Manual)**	
ISO 15190: 12.10					
6.2. Are there safety showers?		✓		**Visual verification and related documentation (Biosafety Manual)**	
6.3. Are personal protective equipment (gloves, gowns, safety glasses) present and properly used?	✓			**Visual verification and related documentation (Biosafety Manual)**	

6.4. Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory?			✓	**Visual verification and related documentation (Biosafety Manual)**	No but no note the signifier
6.5. Is there personal protective clothing for cryogenic storage?				**Visual verification**	Unverified, appliance out of order
Norm: *It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment ... Hand washing stations must be designed and equipped and eye wash stations (or other acceptable methods of rinsing eyepiece) must be available and functional. Spill control equipment and first aid kits must be kept in a well-defined place and their functional status regularly checked.* ***ISO 15190: 5.1***					
7. Waste management					
7.1. Are there signs for waste disposal?		✓		**Related signs and documentation**	In implementation
7.2. Is the waste sorted and collected in the appropriate containers?		✓		**Visual verification (pictogram)**	Only garbage cans for household waste are available No bin for infectious waste or sharps waste, sharp, sharp.
Norm: *The waste must be separated according to biological risk; infectious and non-infectious waste being disposed of in separate containers. Infectious waste must be placed in receptacles that do not leak and be clearly marked with a biological hazard symbol. Sharp instruments and needles should be placed in puncture-resistant containers. Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried* ***ISO 15190 :22***					
7.3. Are Chemical Waste Containers Properly Labelled?		✓		**Visual verification (pictogram)**	Not available
7.4. Are hazardous chemicals disposed of properly?				**Visual verification and documentation related (Waste sorting sheets)**	N/A: Laboratory not used yet
Norm: *All hazardous chemicals must be labelled with the chemical name and clearly marked hazard markings. Flammable chemicals should be stored away from solar radiation and below their flash point, preferably in a well-ventilated area. Flammable and corrosive agents must be separated from each other. Special care must always be taken to manage the safety of hazardous chemicals in the workplace.* ***ISO 15190: 17.1 et 17.3***					
7.5. Are sharp, sharp or sharp objects containers properly used and disposed of?		✓		**Visual verification and related documentation (Biosafety Manual)**	Not available
Norm: *All syringes, needles, lancets or other bleeding devices capable of transmitting an infection must be disposable and disposed of in puncture-resistant containers that are not filled to the brim. Sharps containers must be clearly marked to warn operators of the potential hazard and should be located in areas where sharps are commonly used.* ***ISO 15189: 5.2.10;***					
7.6. Do we find rubbish on the floor?		✓		**Visual verification**	
7.7. Is there a poster for the procedure for waste disposal?		✓		**Visual verification and related documentation (display etc.)**	Not available
8. Existence of occupational health and safety programs at work					
8.1. Risk Communication: Biosafety Manual		✓		**Related documentation (manual, display, etc.)**	Copy not available in the lab

Norm: *The laboratory must have a safety manual that is easily accessible in work areas and is required for all employees to read. The manual must be adapted to the specific needs of the laboratory, it must be reviewed and updated at least once a year by the laboratory management.* ***ISO 15190: 7.4***					
8.2. Staff reads, reviews and follows instructions on practices and techniques, especially those contained in the Safety Manual or Laboratory Manual (mandatory once a year for all staff)		✓		**Related documentation (signature pages)**	Copies of manuals not available in the laboratory
8.3. Medical prevention: vaccinations or necessary examinations offered to staff according to the infectious agents handled: HBV, PEP HIV	✓			**Related documentation (manual, posting, skills assessment sheet, etc.)**	Vaccination of current staff (HR file)
Norm: *Laboratory staff should be offered appropriate vaccinations, particularly for hepatitis B. Staff may refuse to receive the vaccination but must sign a refusal form which will be kept in the employee's personal file.* ***ISO 15190: 11.3*** ***CERMEL SOP : G-023 Accidental Exposure To Potentially Infectious Material V06***					
8.4. Competent medical services contacted for check-ups, medical surveillance and treatment in case of occupational exposure				**Related documentation (manual, display, etc.)**	
Norm: *The laboratory should have a procedure for monitoring known and percutaneous exposures to HIV, HBV, or HCV, mucous membranes, or skin scrapes. The procedure should include clinical and serological evaluation and appropriate prophylaxis.* ***ISO 15190: 9*** ***CERMEL SOP: G-023 Accidental Exposure To Potentially Infectious Material V06***					
9. Technical control systems					
9.1. Is the water distiller in good condition?	✓			**Visual check maintenance sheet**	
Norm: *Preventive maintenance should be performed by operators on all equipment used for testing, including centrifuges, autoclaves, microscopes and safety cabinets.* ***ISO 15189: 4.2.5, 5.3.2***					
9.2. Is the disposal of products in the sink controlled?		✓		**Poster for the disposal of products in washbasins Biosafety Manual**	Miss note indicating the type of waste to be disposed of in the sink Security manual not available
9.3. Is there an arthropod and rodent control program?		✓		**Deratting reports**	
10. General practices and rules					
10.1. Is there a formal ban on eating, drinking, smoking or putting on makeup in the laboratory?		✓		**Visual verification and related documentation (Pictogram, Biosafety Manual)**	No display
10.2. Mechanical pipetting devices, pro pipettes, etc. are they provided and used?	✓			**Visual verification**	
Pipetting and pipetting devices: *Mouth pipetting is strictly prohibited. Pipetting devices, to replace mouth pipetting.* ***WHO Biosafety Manual, 2010, pages 11 and 16***					
10.3. Planning for Staff training course on biosafety		✓		**Related documentation (Training schedule)**	

Norm: *In accordance with national laboratory training plans, each laboratory must have functional training policies and procedures that meet the needs of laboratory personnel through internal and external training.*					
CERMEL SOP : Staff training (L-G-019-V03-EN)					***ISO 15189: 4.12.5, 5.1.6, 5.1.9***
11. General holding of the laboratory					
11.1. Are glass containers placed on the floor?		✓		**Visual verification and related documentation**	
11.2. Are there obvious risks of stumbling?	✓			**Visual verification**	Electrical cables crossing the passages
Norm: *Any clutter should be avoided and the cords should be kept out of the passage areas.*					***ISO 15190: 19.7 et 9.3***
11.3. Is paper towel available on the work surfaces?	✓			**Visual verification and related documentation (SOP: L-CL-002-V04-EN)**	
11.4. Is there a procedure for mechanical handling of glass debris (shovel and brush, pliers, etc...?)	✓			**Visual verification**	
12. Fire safety					
12.1. Are the traffic aisles at least 1m wide?		✓		**Visual verification and related documentation (SOP: Conducting Fire Drills, Emergency Actions and Evacuation Procedure (L-G-028-V01-EN)**	Restricted traffic areas
Norm: *The laboratory should be designed to support high quality work, staff safety and operational efficiency.*					***ISO 15189: 5.2.2***
12.2. Are objects stored on ducts or on electrical appliances?	✓			**Visual verification**	
12.3. Do the devices have frayed wires or are they damaged??		✓		**Visual verification**	
Norm: *Cords, plugs, extension cords and electrical outlets must be kept in good condition and used appropriately. Any congestion should be avoided and cords should be kept out of areas of passage.*					***ISO 15190: 19.7 et 9.3***
13. Heating baths at constant temperature					
13.1. With low water level and overheating switch				**Related documentation (SOP: Immersion thermostat A100 and water bath (L-RL-013-V03-EN) or Machine instructions**	NA
13.2. Constructed of non-combustible material					

Table 2. Basic Laboratory- BSL2

Place:	Date:				
Head of laboratory:					
Person (s) audited					
Controlled Points	**Yes**	**No**	**Partial**	**Means of verification**	**Observations**
1. Microbiological safety station (MSS)					
1.1 Is there certification or validation during the previous year?		✓		**Visual verification and related documentation**	MSS not yet operational
Norm: *A biosafety cabinet must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets require periodic maintenance and must be maintained accordingly.* ***ISO 15190: 16*** ***CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)***					
1.2 Is the surface of the MSS cleaned with a suitable disinfectant at the beginning and end of each manipulation?		✓		**Visual verification and related documentation (maintenance log)**	MSS not yet operational
1.3 Is there a front grille and an unobstructed drain filter on the MSS?	✓			**Visual verification**	
1.4 Can open flames be used in the MSS enclosure?	✓				In deflection with the norm in force and SOP CERMEL
Use of biosafety cabinets in the laboratory *Open flames: Avoid the presence of any open flame in the near-sterile environment inside the enclosure. Flames disrupt the flow of air and can be dangerous if volatile substances are also used. To sterilize bacteriological loops, there are micro burners that are preferable to open flames.* ***WHO Biosafety Manual, page 66*** ***CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)***					
1.6 Is the effectiveness of MSS compromised by ambient air or location?		✓		**Visual verification**	
Use of biosafety cabinets in the laboratory: *BSCs must be installed in locations that are remote from the waypoints and drafts that could interfere with their operation. If possible, a clearance of about 30 centimeters should be provided behind the enclosure and on each side to facilitate access in the event of maintenance operations.* ***WHO Biosafety Manual, page 67***					
1.7 Is MSS used when there is a risk of aerosol formation?				**Visual verification of practices**	N / A laboratory not yet used
Norm: *A biosafety cabinet must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and protection, biosafety cabinets require periodic maintenance and must be serviced accordingly.* ***ISO 15190: 16***					
2. Laboratory					

2.1 Is access restricted to authorized personnel?	✓			**Visual verification and related documentation (display)**	Existence of an access code to the main door
Norm: *Unauthorized access to the laboratory must be strictly limited to avoid unnecessary contact with contaminated areas, reagents or equipment. Unnecessary traffic should not disrupt workflow or distract staff members.* ***ISO 15189: 5.2.7***					
2.2 Biological hazard sign affixed to the laboratory door		✓		**Visual verification and related documentation (display)**	
2.2.1 Exact and up-to-date panel information: ✓ Biosafety level ✓ Anticipated risks (Pathogens) ✓ Researcher in charge ✓ N° to call in case of emergency (day and night):		✓			
2.2.2 Panel readable and in good condition?		✓			
2.3 Are all doors constantly closed?		✓			P3 doors Open
3. Decontamination					
3.1 Are there any disinfectants specific to the microorganisms involved??	✓			**Visual verification and related documentation**	Bleach available
Norm: *The work area should be inspected regularly for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all benches and work surfaces must be disinfected at the beginning and end of each work cycle. All accidental spills must be immediately controlled and disinfected work surfaces.* ***ISO 15189: 5.2.10; ISO 15190 :13*** ***SOP CERMEL: Cleaning and disinfection of surfaces (L-ML-039-V01-FR)***					
3.2 Is the laboratory supervisor notified if infectious material is widespread or involved in an accident?		✓		**Tools: Exposure report (L-G-023-T3-V03-EN)**	No documentation on site
3.3 Are work plans cleaned before and after each handling, daily or if a product has been spilled?				**Visual verification and related documentation (maintenance log)**	
Plans de travail: *Work plans must be decontaminated if they have been contaminated with potentially dangerous products and at the end of the working day.* ***WHO Biosafety Manual: Laboratory Design page 12*** ***CERMEL SOP: Cleaning of CERMEL Facilities and Laboratories (L-G-040-V02-EN)*** ***CERMEL SOP: Accidental exposure to potentially infectious material (L-CL-002-V04-EN)***					
4. Handling of contaminated waste					
4.1 Good use of contaminated waste containers?			✓	**Visual verification**	Waste are autoclaved but no bins available for biomedical waste
4.2 No bins filled up to the brim?				**Visual verification**	NA: no bins
4.3 Trash bins properly labelled and closed?				**Visual verification**	NA: no bins

4.4 Crops and other wastes subject to regulation properly decontaminated before disposal?	✓			**Visual verification and related documentation (Waste management)**	Autoclave available in the room
Norm**: Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried.* ***ISO 15190 :22					
4.5 Transport in sealed, solid and sealed containers of decontaminated material outside the laboratory, in accordance with local regulations	✓			**Visual verification**	
5. Individual protection					
5.3 Wearing gloves for handling infectious biological material or contaminated equipment			✓	**Visual verification and related documentation (Biosafety Manual)**	Gloves available but laboratory still not operational
5.4 Facial protection when working on infectious material outside MSS				**Visual verification and related documentation (Biosafety Manual)**	N/A
Norm:** It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment. The list above is a partial list of the necessary items.* ***ISO 15190: 5.1					
5.5 Wash hands after removing gloves and before leaving the laboratory		✓		**Visual verification and related documentation (tool: hand washing L-G-041-R2-V01-EN)**	No display for this purpose
Norm:** Hand washing stations should be designed and equipped and eyewash stations (or other acceptable eye washing methods) should be available and functional.* ***ISO 15190: 5.1					
6. Practice					
6.1 Are auto-disable or disposable syringes used for work on infectious agents?				**Visual verification of practices**	NA
Aerosol production: *All techniques used must minimize the formation of aerosols and droplets.* ***WHO Biosafety Manual: Procedure page 11***					
6.2 Infectious specimens are transported out of PSM in approved containers in accordance with the transport regulations for this type of product	✓			**Visual verification and related documentation (Biosafety Manual, SOP)**	
Transport of samples**:* *To avoid leaks or accidentally spilled material, secondary containers, such as boxes, with racks should be used so that the container containing the sample does not spill, in accordance with national or international regulations.* ***WHO Biosafety Manual: pages 12 and 77					
7. Convenience					
7.1 Are sinks installed near the exit of the laboratory?	✓			**Visual verification**	
Norm:** Hand washing stations should be designed and equipped and eyewash stations (or other acceptable eye washing methods) should be available and functional.* ***ISO 15190: 5.1					

Table 3. Containment laboratory -BSL3

Place:	Date:				
Head of laboratory:					
Controlled Points	**Yes**	**No**	**Partial**	**Means of Verification**	**Observations**
Overview: *Containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 microorganisms and high volumes or concentrations of Risk Group 2 microorganisms that are more susceptible to handling. to cause the diffusion of aerosols.* ***WHO Biosafety Manual, page 22***					
1. Laboratory design					
1.1. Is the laboratory separated from the normal crossing points of the building?	✓			**Visual verification**	
1.2. Does access to the laboratory through a vestibule have self-closing doors?	✓			**Visual verification**	• Door not operational on the day of the audit
1.3. Are gaskets installed or can be installed at all crossings for laboratory decontamination?	✓			**Visual verification**	
2. Room air not recycled and evacuated from occupied areas	✓			**Visual verification**	• Non-operational ventilation system on the day of the audit
2.1. Regulated ventilation system to control the direction of air circulation	✓			**Visual verification (manometer)**	• Non-operational ventilation system on the day of the audit
Design and layout of the laboratory: *Laboratory to be separated from unregulated passage areas* *The vestibule doors must be self-closing and interlocked so that only one door can be opened at a time* *The laboratory must be able to be hermetically closed to be decontaminated* *The ventilation system must create a stream of air directed from the access area to the interior of the room. A visual control device, whether or not equipped with an alarm, shall be installed so that personnel can ensure that the airflow is always correctly directed* *The ventilation system must be constructed in such a way that the air leaving the containment laboratory - Biosafety Level 3, is not recycled in other areas of the building* ***WHO Biosafety Manual, page 23***					
3. Individual protection					
3.1. Wearing closed blouses on the front in the laboratory		✓		**Visual verification**	
3.2. Wear protective clothing limited to laboratory premises		✓		**Visual verification and related documentation (display)**	No display
3.3. Pedestal, elbow or self-operated washbasin		✓		**Visual verification**	No washbasin in the room
Norm: *It is the responsibility of management to provide appropriate personal protective equipment (gloves, gowns, goggles, etc.) in a usable condition. Laboratory personnel must at all times use PPE in the laboratory. Protective clothing should not be worn outside the laboratory. Torn or contaminated gloves should be replaced immediately and not washed for reuse.* ***ISO 15190: 12***					

Code of good practice *It is forbidden to wear protective clothing outside the laboratory.* *A washbasin that can be controlled without the help of the hands will be placed near each exit door.* *Protective clothing to be worn in the laboratory must be of the following type: aprons, gowns, lab coats, cleaning suits, overalls, headdresses and, where appropriate, shoe covers and special shoes.* *Regular lab coats that button in front are not suitable, as well as sleeves that do not fully cover the forearms.* ***WHO Biosafety Manual, page 22***					
4. Hands protections					
4.1. Wearing double gloves for working with infectious material and equipment or worktops that may be contaminated				**Visual verification of practices**	N / A non-operational laboratory
5. Respiratory protection					
5.1. Wearing respiratory protection by all laboratory personnel when aerosols are not safely contained in a MSS	✓			**Visual verification of practices**	N95 masks available
Code of good practice *Wearing a respirator may be necessary for some handling or when working on animals carrying certain pathogens* ***WHO Biosafety Manual, page 22***					
6. Practice					
6.1. Staff warned of specific risks related to the agent or infectious agents		✓		**Visual verification of practices and related documentation (biosecurity manual, display)**	Manual not available No display
Norm: *The laboratory must have a safety manual that is easily accessible in work areas and* ***is required for all employees to read****. The manual must be adapted to the specific needs of the laboratory, it must be reviewed and updated at least once a year by the laboratory management.* ***ISO 15190: 7.4***					
6.2. Annual updates to staff or additional training if changes are made to certain techniques				**Related documentation (skills assessment sheet, training plan)**	
6.3. Autoclaving of all waste before disposal	✓			**Visual verification of practices and related documentation (Biosafety Manual,)**	Autoclave available in the room
Norm: *The waste must be separated according to biological risk; infectious and non-infectious waste being disposed of in separate containers. Infectious waste must be placed in receptacles that do not leak and be clearly marked with a biological hazard symbol. Sharp instruments and needles should be placed in puncture-resistant containers. Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried.* ***ISO 15190 :22***					
7. Health surveillance					
7.1. Staff warned of specific risks related to the agent or infectious agents		✓		**Visual verification of practices and related documentation (biosecurity manual, display)**	Manual not available No display

Medical and health surveillance

1. The medical examination is mandatory for all laboratory personnel working in the containment laboratory. It should include an anamnesis in search of medical history and a physical examination to check if the person is medically fit to perform this type of professional activity.

2. If the medical check-up is satisfactory, the person concerned will receive a medical card attesting that he / she is employed in an establishment where a level 3 biological safety containment laboratory is located. This card, which the card holder must always wear, will include the holder's photograph and must be stowed in a wallet or card holder. It should also indicate the name of the person or persons to contact in case of problems, who will be designated locally, but who could be for example, the director of the laboratory, the medical adviser or the delegate for biosafety.

WHO Biosafety Manual, page 26

Auditor's Name & Signature: Hutch-l'herbner Nzenguéle [signature]

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End Date of control 30th April 2018