

Audit on biosafety

Table 1.Basic Laboratory-BSL1

entation procedures. The laboratory must be ISO 15190: 6.3.1	carry out quality control and docume	ne ability of staff to ature ranges.	iff and the	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
Lighting in each room	Visual verification		<	2.3. Are the rooms adequately lighted?
WHO Biosafety Manual, 2010, page 14	o withstand moderate heat.	lvents and be able t	ganic so	Coating of the benches: Countertop work surfaces must be waterproof, resistant to disinfectants, acids, alkalis and organic solvents and be able to
	Visual verification		<	2.2. Is bench top coating waterproof and resistant to acids, bases, organic solvents and heat?
	Visual verification		<	2.1. Are the shelves securely fixed?
				2. Laboratory design
WHO Biosafety Manual, 2010, page 12			И	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
ns are handled. the premises WHO Biosafety Manual, 2010, pages 10 and 22	g to risk group 2 or higher groups are handled. anager responsible for access to the premises WHO Biosafei	organisms belongin of the laboratory m	e micro-	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 handlea 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 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 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
	Visual verification (Pictogram)	•		1.3. Are laboratory equipment properly marked (biological hazard, radioactivity, toxicity, etc.)?
 No copy of the biosecurity manual on site Guidelines for hand hygiene are not displayed 	Visual Verification (Pictogram), Biosafety Manual (read and signed)			1.2. Are biosecurity guidelines existing and known?
 No adequate marking to know biological hazard pictogram on all rooms, appliances, autoclaves, centrifuges 	Visual verification, MSDS and / or implementation cards	•		1.1. Is signalling appropriate: hazardous substances?
				1. Laboratory
Observations	Means of verification	No Partial	Yes	
	11 Imer , Post - doc	Turi Ushi	100	and post: Dr Haraka Abe
			18	Place: CERMEL Joint Research Laboratory / Nagasaki University Date: 30 April 2018 Head of laboratory: D. Markey 12 Head of laboratory:
		1000	3	



NA: Absence of chemicals in the laboratory	Visual verification (Pictogram)			4.2. Are carcinogenic, radioactive or biohazardous substances indicated by an external mark?
boratory reagents and blood products should	areas, especially in the cold room. La	atory storage (in the labor	worm: Personnel JooastuJJ's 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 1519D: 11.1
No food in the laboratory. However, no signage prohibiting the storage of food in refrigerators	Visual verification	٠,		4.1. Are foods for human consumption stored in refrigerators and freezers?
				4. Kerrigerators, treezers, cold rooms
ISO 15190: 17.1 et 17.3				
orrosive agents must be separated from each	ll-ventilated area. Flammable and co	erably in a we	point, prefi	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.
NA: No stock of chemicals in the lab	Visual verification and related documentation (Reagent storage sheets)			3.7. Are flammable products stored in secure or explosion proof units?
ISO 15190: 17.1 et 17.3			markings.	All hazardous chemicals must be Labelled with the chemical name and clearly marked hazard markings.
Missing danger marking		1000		Inhelling of chemicals:
Bleach: lack of initials, date of preparation and expiration	Visual verification	<		3.6. Are the solutions correctly labelled?
	Visual verification	<		3.5. Do chemical containers remain open during and after use?
	Visual verification	\ 		- 1
	Visual verification	•		3.3. Are dangerous products stored above eye level?
	storage sheets)			
	Visual verification and related documentation (Reagent		<	3.2. Are the products properly separated?
storage				
Provide secure cabinet for large quantity	storage sheets)			
Limited quantity chemical (eg bleach, EtOH)	Visual verification and related			3.1. Are flammable products stored in appropriate cabinets?
and formal manners bag caro				3. Chemicals
WHO Biosafety Manual, 2010, mage 15	ge areas.	and the passa	he benches	The storage spaces must be able to receive the current equipment, so as to avoid the bulk of the benches and the passage areas.
instruments	storage sheets)			Characteristics
Congestion: presence of devices on ways, and laboratory equipment on laboratory	Visual verification and related documentation (Reagent		٠,	2.4. Are storage spaces adequate and properly used?



Generator + UPS Generator + UPS ded and cords should be kept out of areas of passage. ISO 15190: 19.7 et 9.3 fety ISO 15190: 12.10 related fety	visual verification and related documentation (Biosafety Manual) Visual verification and related documentation (Biosafety Manual)	<	_	
Generator + UPS Generator + UPS led and cords should be kept out of areas of passage. ISO 15190: 19.7 et 9.3 I related fety ISO 15190: 12.10	Visual verification and documentation (Biosaf Manual)			6.2. Are there safety showers?
Generator + UPS Generator + UPS led and cords should be kept out of areas of passage. ISO 15190: 19.7 et 9.3 I related fety	visual verification and documentation (Biosaf Manual)			
Generator + UPS ded and cords should be kept out of areas of passage. ISO 15190: 19.7 et 9.3	ongestion should be avoids		_ <	6.1. Are there eye rinses in the laboratory?
Generator + UPS Generator + UPS ded and cords should be kept out of areas of passage. ISO 15190: 19.7 et 9.3	ongestion should be avoids			6. Personal protective equipment
Generator + UPS		opriately. Any	d used appi	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
NA	Visual verification		<	5.7. Are there device protections against power interruptions and / or overloading?
	Visual verification			5.6. Do outlets close to water supply comply with local regulations?
	Visual verification		<	5.5. Are plugs or inserts with connections overloaded?
	Visual verification	<		5.4. Are outlets and other connections near sinks, under showers, etc?
	Visual verification		<	5.3. Are the wafers connected to the floor?
	Visual verification		<	5.2. Are there electric cables on the ground?
Many extensions passing crossing areas, high accident risk	Visual verification	\		5.1. Are extension cords properly placed in theatres?
				5. Electrical equipment
ISO 15189: 4.2.5, 5.3.2	res, autociaves, microscope	namy centrijai	resung, inc	CERMEL SOP: General usage and maintenance of microscopy (L-G-027-V06-EN)
or and rafety rabinate	autoclause microscope	hading contrifin	torting inc	Name Description and interest in the state of the state o
ent	Visual verification and documentation (equipment maintenance log, annual maintenance labels)			4.4. Is there a preventive or annual maintenance of the devices?
Note: No maintenance to date, newly		The state of the s		CEVINITY 201. Monitornia temberatures finades and freezers F-0-052-404-FM
fications or where they are likely to influence the quality	h the corresponding specifi	accordance wi	nditions in	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» CERNEL SOP: Manifering temperatures fridges and freezers (I-G-078-VNA-EN)
	log)			
Presence of thermometers in each room Log of temperature monitoring not	Visual verification and documentation (temperature	<		4.3. Is there a temperature management system?



for cryogenic storage? for cryogenic storage? for panagement to ensure that the laboratory is equipped with standard safety tory management to ensure that the laboratory is equipped with standard safety sof rinsing eyepiece) must be available and functional. Spill control equipment of the property is equipped with standard safety sof rinsing eyepiece) must be available and functional. Spill control equipment of the property is equipped with standard safety standard special control equipment of the property is equipped with standard standard special special of instance and non-infectious waste being disposed of insulting to biological risk; infectious and needles should be placed in puncture-resentially infectious material. To avoid injury from exposed waste, infectious waste reposed with the chemical name and clearly marked hazard markings. Flammable flammable and corrosive agents must be separated from each other. Special control devices capable of transmitting an infection must be disposable and the waste disposable and the potential hazard and should be located in areas where supposed waste disposal? Very Labelled with the chemical name and clearly marked hazard markings. Flammable flammable and corrosive agents must be separated from each other. Special control waste disposable and the located in areas where supposed waste disposable and the located in areas where supposed waste disposal?	Copy not available in the lab	Related documentation (manual, display, etc.)	<	8.1. Risk Communication: Biosafety Manual
Are overalls, in the cores, gloves and other protective clothing or excessories Windows and entire the signifier Windows and other protective clothing for cryogenic storage? Visual verification It is the responsibility of the inharcatory interpretation and related very thing protective clothing for cryogenic storage? Visual verification Visual verification Visual verification Visual verification Visual verification In implementation Only garbage and the designed and equiphed		•		o. Existence of occupational health and safety programs at work
Are overalls, become suite the blace characy? Is there personal protective clothing for cryogenic storage? Is the represental protective clothing for cryogenic storage? Is the represental protective clothing for cryogenic storage? It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard style equipment. Hard working stations for other expectable methods of management to ensure that the laboratory is equipped and syne is strikened for characteristic for other acceptable methods of management to ensure that the laboratory is equipped and syne is strikened. Spill control equipment and first aid kits must be kept in a well-defined place and their functional status for the easily injectious material. To avoid injury from exposed west, injectious waste must be indeed to the surface of the separate documentation. Only gerbage cant for household waste are than the easily makes and another early before any surface of the separate containers. Injectious waste on status to disposal to decontrainment only potentially injectious materials. To avoid injury from exposed west, injectious waste must be included in a pit or buried waste or the before any expensive expensive that documentation in the easily for the potentially injectious materials. To avoid injury from exposed west, injectious waste entitles to make a pit or buried waste or the surface of the surface of the expensive expen	Not available		•	7.
Are overalls, and costs gloves and other protective clothing or accessories Are overalls, brighted biboratory? In their personal protective clothing for cryogenic storiage? Are overalls, as to consider the biboratory? In their personal protective clothing for cryogenic storiage? Are stated as exponsibility of the laboratory management to ensure that the informative is equipped and eye equipment. Hand weathing stations must be designed and eye equipment and first old kits must be designed and eye equipment and first old kits must be designed and eye traffic the country of the master of the protection of the protection of the clothy marked with a biological house of properly in the clothy marked with a biological house of properly in the cloth for modernial equipment and protection and decomentation and experience with a biological house of properly in the clothy marked with a biological house of properly in the cloth for modernial equipment and protection where the segment of decomentation and decomentation and the cloth which a biological house of properly in the clothy marked with a biological house of properly in the cloth for infectious waste or should be placed in the expendent of the clothy marked with a biological house of properly in the clothy marked house of properly in the chemical name of properly in the chemical name of properly in the chemical name and containers from the separated away from solar radiation and documentation and documentation and documentation and documentation and the properly in the chemical name of properly in the chemical name of properly in the chemical name and clearly marked house the clothy marked over from the expendence of the potential hazard and should be located in areas where sharps are commonly used. Visual verification and related with a pit or binded to war operators of the potential hazard and should be located in a reach other. Special care must always be taken to manage the safety of hazardous chemicals in the safety of hazardous demicals in the safety of		Visual verification	<	
Are overalls, abcoars, goves and other protective dothing or accessories with outside the laboratory? Is these personal protective dothing for cryogenic storage? If it is the responsibility of the laboratory management to ensure that the baboratory is equipped with standard sufery equipment Hand washing stations must be designed and equipped and eye buy checked. Is the responsibility of the laboratory management to ensure that the baboratory is equipped with standard sufery equipment Hand washing stations must be designed and equipped and eye buy checked. Is the responsibility of the laboratory management to ensure that the baboratory is equipped with standard sufery equipment Hand washing stations must be designed and equipped and eye to live the segment of the laboratory management to disposal? Waste management We have segment to describe methods of mising eyapiecal must be available and functional status. Is the waste of the personal collected in the appropriate containers? Waste management We waste insure the segment of the laboratory management to all first aid kits must be kept in a well-defined place and their functional status. Is the waste out of order to decide the properties of must be outside the submitted of the segment and first aid kits must be kept in a well-defined place and epice and epice and their functional status. Is the waste outside the submitted of the segment and first aid kits must be kept in a well-defined place and epice and their functional status. Is the waste outside the submitted of the segment and first aid kits must be kept in a well-defined place and their functional status. In implementation Only garbage cans for household waste and submitted in part of the status waste outside the segment and first aid kits must be kept in a well-defined place and sharps are and submitted in a pit or burief on a waste outside the place of the containers must be laborated to a biological hazard and submitted and submitted and place cans for household waste and submit	ISO 15189: 5.2.10;	here sharps are commonly used.	ocated in areas wh	7.6. Do we find rubbish on the floor?
Are overalls, lab coats, gloves and other protective dothing or accessories Wistal verification Wistal verification Manual	nt containers that are not filled to the brim.	le and disposed of in puncture-resistant	must be disposab	Sharps containers must be clearly marked to warn apparatus of the state of transmitting an infection
Are overalls, be coats, gloves and other protective clothing or accessories Warn outside the laboratory? Is there personal protective clothing for cryogenic storage? It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment and first aid kits must be kept in a welf-defined place and their junctional status (it is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment and first aid kits must be kept in a welf-defined place and their junctional status (it is the responsibility of the laboratory management to ensure that the laboratory is equipped and equipped and equipped and eye value for other acceptable methods of rinsing eyepiece) must be available and first andard safety equipment and first aid kits must be kept in a welf-defined place and their junctional status (it is the responsibility of the laboratory management to any checked. Waste management Waste management Waste management In implementation Only garbage cars for household waste are evaluable and collected in the appropriate containers? Visual verification (pictogram) Only garbage cars for household waste are available waste must be sparated according to biological hazard symbol. Sharp instruments and needles should be placed in a puncture-restrict management, infectious waste must be placed in neceptacles that do not to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incherated, burned in a pit or bursed so the sharp. Sharp, s	Not available	visual verification and related documentation (Biosafety Manual)	٠,	7.5. Are sharp, sharp or sharp objects containers properly used and disposed of?
Are overalls, coveralls, do cotats, gloves and other protective clothing or accessories worn outside the laboratory? Is there personal protective clothing for cryogenic storage? It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment. It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment and first oid kits must be kept in a well-defined place and their functional status for which the characteristic process of missing eyepiece) must be available and functional. Spill control equipment and first oid kits must be kept in a well-defined place and their functional status. ### Waste management Waste management Wester management Are there signs for waste disposal? ### Waste management Wester signs for waste disposal? Only garbage cans for household waste are available of inseparated according to biological risk; infectious and non-infectious waste being disposed of in separate containers. Infectious waste must be placed in puncture-resistant containers. Infectious waste must be placed in price onto sharps waste, infectious waste must be autoclaved to disposal to decontainers properly Labelled? Visual verification (pictogram) Not available No but no note the signifier waste file on the designed and equipped and equ	ry from solar radiation and below their flash age the safety of hazardous chemicals in the ISO 15190: 17.1 et 17.3	imable chemicals should be stored away cial care must always be taken to mana;	n each other. Spec	point, preferably in a well-ventilated area. Flammable and corrosive agents must be separated fro workplace.
Are overalls, becoats, gloves and other protective clothing or accessories worn outside the laboratory? Sthere personal protective clothing for cryogenic storage? Visual verification Substantiation (Biosafety Visual verification Unverified appliance out of order Visual verification Visual verification Unverified appliance out of order Visual verification Visual verifica		related (Waste sorting sheets)		Norm: All hazardous chemicals must be labelled with the chamical name and closely with the
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Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory? Is there personal protective clothing for cryogenic storage? 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 eye larly checked. Is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment and first aid kits must be kept in a well-defined place and their functional status. Iso 15190: 5.1 Waste management Are there signs for waste disposal? Are there signs for waste disposal? Are there signs for waste disposal? In implementation Only garbage cans for household waste are waste onto infectious waste onto infectious waste onto infectious waste onto infectious waste onto laboratory. In placed in puncture-resistant containers. Infectious waste and sharps receptacles must be autoclaved 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 is pit or buried in pit or buried is pit or buried in pit or buried is pit or buried is pit or buried in pit or buried is pit or buried is pit or buried in pit or buried is pit or buried is pit or buried in pit or buried in pit or buried is pit or buried in pit or bu	Not available		Y	- 1
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Are overalls, coveralls, lab coets, gloves and other protective clothing or accessories worn outside the laboratory? Is there personal protective clothing for cryogenic storage? 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 equipped with standard safety equipment and first aid kits must be kept in a well-defined place and their functional status for there signs for waste disposal? Waste management Are there signs for waste disposal? Wisual verification Univerified, appliance out of order is the designed and equipped and equipped with standard safety equipment and first aid kits must be kept in a well-defined place and their functional status is the waste sorted and collected in the appropriate containers? Wisual verification Visual verification Univerified, appliance out of order visual verification Visual verification Visual verification Visual verification No but no note the signifier work and related No but no note the signifier work and related No but no note the signifier work and related No but no note the signifier work and related No but no note the signifier work and pocumentation Univerified, appliance out of order Visual verification Univerified appliance out of order Visual verification No but no note the signifier	ste must be placed in receptacles that do not e and sharps receptacles must be autoclaved pit or buried	of in separate containers. Infectious was ure-resistant containers. Infectious waste waste must be incinerated, burned in a ı	te being disposed on placed in puncture placed in puncture placed in puncture placed in the placed i	leak and be clearly marked with a biological hazard symbol. Sharp instruments and needles should. prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposes
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Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory? Is there personal protective clothing for cryogenic storage? 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 larly checked. Washual) Visual verification Visual verification Unverified, appliance out of order votations 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 Waste management Waste management Related signs and In implementation	Only garbage cans for nousehold waste are available No bin for infectious waste or sharps	Visual verification (pictogram)	•	7.2. Is the waste sorted and collected in the appropriate containers?
Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory? Visual verification and related worn onte the signifier worn outside the laboratory? Visual verification (Biosafety Manual)	Only garbage case for barrabald			
Are overalls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory? Is there personal protective clothing for cryogenic storage? Is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment and first aid kits must be kept in a well-defined place and their functional status. Waste management Visual verification (Biosafety documentation (Biosafety Manual) Visual verification (Manual) Visual verification (Biosafety Manual) Visual verification (Manual) Visual verification (Biosafety Manual) Visu	In implementation	Related signs and documentation	<	7.1. Are there signs for waste disposal?
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Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory? Wisual verification and related documentation (Biosafety Wisual verification Wisual verification Unverified, appliance out of order	tions must be designed and equipped and eye well-defined place and their functional status ISO 15190: 5.1	safety equipment Hand washing stati ment and first aid kits must be kept in a v	oed with standard Spill control equipr	wash stations (or other acceptable methods of rinsing eyepiece) must be available and functional. regularly checked.
Visual verification and related documentation (Biosafety Manual)	Unverified, appliance out of order	Visual verification		Norm: It is the responsibility of the laboratory magazine storage?
Visual verification and related documentation (Biosafety		Manual)		A S Is thorse possessed protection of letting for
	No but no note the signifier	Visual verification and related documentation (Biosafety	<	6.4. Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory?



	Related documentation (Training schedule)	<		3. Planning for Staff training course on biosafety	10.3.
WHO Biosafety Manual, 2010, pages 11 and 16	W			Pipetting and pipetting devices: Mouth pipetting is strictly prohibited. Pipetting devices, to replace mouth pipetting.	Pip. Mo
	Visual verification		<	.2. Mechanical pipetting devices, pro pipettes, etc. are they provided and used?	10.2.
No display	Visual verification and related documentation (Pictogram, Biosafety Manual)	<		.1. Is there a formal ban on eating, drinking, smoking or putting on makeup in the laboratory?	10.1.
				. General practices and rules	10.
	Deratting reports	<		3. Is there an arthropod and rodent control program?	9.3.
Miss note indicating the type of waste to be disposed of in the sink Security manual not available	Poster for the disposal of products in washbasins Biosafety Manual	•		?. Is the disposal of products in the sink controlled?	9.2.
ety cabinets. ISO 15189: 4.2.5, 5.3.2	iges, autoclaves, microscopes and safe	, including centrif	testing	Norm: Preventive maintenance should be performed by operators on all equipment used for testing, including centrifuges, autoclaves, microscopes and safety cabinets.	No
	Visual check maintenance sheet		<	L. Is the water distiller in good condition?	9.1.
				Technical control systems	9.
150 15190: 9				CERMEL SOP: G-023 Accidental Exposure To Potentially Infectious Material V06	CEH
mucous membranes, or skin scrapes. The procedure snowa include clinical and	ICV, mucous membranes, or skin scra	s to HIV, HBV, or h	posures	Norm: The laboratory should have a procedure for monitoring known and percutaneous exposures to HIV, HBV, or HCV, serological evaluation and appropriate prophylaxis.	ser
41	Related documentation (manual, display, etc.)			Competent medical services contacted for check-ups, medical surveillance and treatment in case of occupational exposure	8.4
				CERMEL SOP : G-023 Accidental Exposure To Potentially Infectious Material V06	Œ
efusal form which will be kept in the ISO 15190: 11.3	eive the vaccination but must sign a n	ff may refuse to re	B. Staf	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 15	em,
Vaccination of current staff (HR file)	Related documentation (manual, posting, skills assessment sheet, etc.)		<	 Medical prevention: vaccinations or necessary examinations offered to staff according to the infectious agents handled: HBV, PEP HIV 	8.3.
Copies of manuals not available in the laboratory	Related documentation (signature pages)	<		 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) 	8.2.
pted to the specific needs of the laboratory, it ISO 15190: 7.4	rees to read. The manual must be ada	uired for all emplo	d is requ	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	Mu Mo

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.

	EN) or Machine instructions			
	Immersion thermostat A100		2. Constructed of non-combustible material	13.2.
NA	Related documentation (SOP:		1. With low water level and overheating switch	13.1.
			Hea	13.
Is should be kept out of areas of passage.	congestion should be avoided and cord	used appropriately. Any		
	Visual verification	×	the Cords place actangle and electrical and all the damaged it	Norn
	Visual verification			12.3
ISO 15189: 5.2.2			2. Are objects stored on directs or an electrical analismonal	12.2
		rtional efficiency.	worm: The haboratory should be designed to support high quality work, staff safety and operational efficiency.	MOLL
	Emergency Actions and Evacuation Procedure (L-G- 028-V01-EN)		The laboratory is the label of	
	Conducting Fire Drills,	<	.1. Are the traffic aisles at least 1m wide?	12.1.
Restricted traffic areas	Visual verification and related documentation (SOP:			
		-	. Fire safety	12.
	Visual verification	<	1 +	11.4.
	V04-EN)			1
	Visual verification and related documentation (SOP: L-CL-002-	\	3. Is paper towel available on the work surfaces?	11.3.
ISO 15190: 19.7 et 9.3				
Fire passages			Norm: Any clutter should be avoided and the cords should be kept out of the passage areas.	Nor
Flectrical cables crossing the passages	Visual verification	<	1.2. Are there obvious risks of stumbling?	7.7.
	Visual verification and related documentation	<		11.1.
			11. General holding of the laboratory	E
ISO 15189: 4.12.5, 5.1.6, 5.1.9			CERMEL SOP: Staff training (L-G-019-V03-EN)	CER
			external training.	ext

2. Laboratory



Table 2. Basic Laboratory- BSL2

Head of laboratory: Person (9) audited Controlled Points: 1. Microbiological safety station (MSS) 1. Microbiological safety station (MSS) 1. In their certification or validation during the previous year? 1. In the biosofety cobinet must be used to prevent exposure to persons from specimens or controllous organisms. To ensure proper operation and omplete protection, biological sofety cabinets require persons of the MSS cleaned with a suitable disinfectant at the beginning and end death manipulation? 1.1 Is there a front grille and an unobstructed drain filter on the MSS? 1.2 Is there a front grille and an unobstructed drain filter on the MSS? 1.3 Is there a front grille and an unobstructed drain filter on the MSS? 1.4 Can open flames be used in the MSS enclosure? 1.5 Is the encinological loops, there are mirro burners that are preferable to open flames. Novid the prevence of any pen flames that are preferable to open flames. Void the prevence of any pen flames that are preferable to open flames. 1.6 Is the efficitiveness of MSS componitised by ambient air or location? 1.6 Is the efficitiveness of MSS componitised by ambient air or location? 1.6 Is the efficitiveness of MSS componitied by ambient air or location? 1.6 Is the efficitiveness of MSS componitied by mibient air or location? 1.7 Is MSS used when their is a risk of aerosol formation? 1.7 Is MSS used when their open are not preferable to open flames are preferable to could interfere with their operation. If possible, a dearance of about 30 centimeters should be provided behind the enclosure of any pen flame access in the event of mointenance operations. 1.8 Is the distribution of provided behind the event of mointenance operations. 1.8 Is the statement of the burners that a behandary: 1.8 Is the interference of the middle of the event of mointenance operations. 1.8 Is the interference of the middle of the event of mointenance operations. 1.8 Is the interference of the middle of the event of mointenance operations. 1.8 Is the interfe	To ensure proper operation and protection, biosafety cabinets require periodic	nsure proper operation a		contagious or	North A historiaty carbinat must be used to prought expected to acrossle from specimens or contaging organisms
safety station (MSS) safety station (MSS) safety station or validation during the previous year? Althorophological Safety Stations (L-G-045-V01-FR) grille and an unobstructed drain filter on the MSS? The presence of any open florms in the laboratory: the presence of any open flormers that are preferable to open flames. MASS not yet operational related documentation (maintenance log) Wisual verification and complete protection, biological sofety cobinets required not prevent synotype to perational at the beginning and end Wisual verification and complete protection, biological sofety cobinets required having the prevent synotype to perational related documentation (maintenance log) grille and an unobstructed drain filter on the MSS? Wisual verification and complete protection, biological sofety cobinets required having the prevent of protection and complete protection, biological sofety cobinets required having the flore of protection and complete protection, biological sofety cobinets required having the prevent of maintenance log) grille and an unobstructed drain filter on the MSS? Wisual verification and complete protection, biological sofety cobinets of the flore of any open flore and sofety of any open flore and sofety open flore and sofety open flore and sofety open flores. WHO Biosofety Manual, page of Microbiological sofety Stations (L-G-045-V01-FR) WHO Biosofety Manual, page with their operation. If possible, a clearance of about 3D centimeters should be provided behind to sold interfere with their operation. If possible, a clearance of about 3D centimeters should be provided behind to sold interfere with their operation. If possible, a clearance of about 3D centimeters should be provided behind to sold interfere with their operation.		Visual verification of practices			1.7 Is MSS used when there is a risk of aerosol formation?
Yes No Partial Means of verification Visual verification and related documentation and related documentation and related documentation (maintenance log) Visual verification Visual verification Visual verification Visual verification Visual verification	about 30 centimeters should be provided behind the WHO Biosafety Manual, page 67	^c possible, a clearance of a	ir operation. If	erfere with the	Use of biosafety cabinets in the laboratory: BSCs must be installed in locations that are remote from the waypoints and drafts that could inte enclosure and on each side to facilitate access in the event of maintenance operations.
safety station (MSS) Ves No Partial Means of verification and continuents to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets requirements and an unobstructed drain filter on the MSS? Iso 15190: Visual verification and complete protection, biological safety cabinets requirements or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets requirements or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets requirements on the MSS cleaned with a suitable disinfectant at the beginning and end Visual verification and complete protection, biological safety cabinets requirements on the MSS not yet operational related documentation (maintenance log) In deflection with the norm in force and be dangerous if volatile substances are also used. To without one or micro bunners that are preferable to open flames. WHO Biosofety Manual, page of Microbiological Safety Stations (L-G-045-V01-FR)		Visual verification		<	1.6 Is the effectiveness of MSS compromised by ambient air or location?
safety station (IMSS) safety station (IMSS) ation or validation during the previous year? To ensure proper operation and complete protection, biological sofety cabinets required accordingly. Solution of the MSS cleaned with a suitable disinfectant at the beginning and end on the MSS? To ensure proper operation and complete protection, biological sofety cabinets required accumentation (maintenance log) Wisual verification and complete protection, biological sofety cabinets required accumentation (maintenance log) Wisual verification Visual verification MSS not yet operational related documentation (maintenance log) Visual verification In deflection with the norm in force and soft the norm in force and soft the norm in force and soft the maintenance log (provided in the MSS) enclosure?	ngerous if volatile substances are also used. To WHO Biosafety Manual, page	low of air and can be dang	s disrupt the f	closure. Flame	Use of biosafety cabinets in the laboratory Open flames: Avoid the presence of any open flame in the near-sterile environment inside the encesterilize bacteriological loops, there are micro burners that are preferable to open flames. CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)
safety station (MSS) Yes No Partial Means of verification Observations To ensure proper operation and complete protection, biological safety cobinets require the MSS cleaned with a suitable disinfectant at the beginning and end on unobstructed drain filter on the MSS? Yes No Partial Means of verification Means of verification and verification and verification and complete protection, biological safety cobinets required documentation and complete protection, biological safety cobinets required documentation (maintenance log) Yes No Partial Means of verification and visual verification and complete protection, biological safety cobinets required and influence log (maintenance log) Yes No Partial Means of verification and visual verification and complete protection, biological safety cobinets required and influence log (maintenance log) Yes No Partial Means of verification and visual verification and complete protection, biological safety cobinets required and influence log (maintenance log)	In deflection with the norm in force and SOP CERMEL				1.4 Can open flames be used in the MSS enclosure?
regrety station (MSS) Yes No Partial Means of verification MSS not yet operations Wisual verification and complete protection, biological safety cabinets require and must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets require and must be maintained accordingly. Iso 15190: Wisual verification and complete protection, biological safety cabinets require and must be maintained accordingly. Wisual verification and related documentation and related documentation and complete protection, biological safety cabinets requirements and related documentation and maintained accordingly. Wisual verification and maintained accordingly. Wisual verification and maintained accordingly. Wisual verification and maintained maintained accordingly.		Visual verification			1.3 Is there a front grille and an unobstructed drain filter on the MSS?
safety station (MSS) Safety station (MSS) The station or validation during the previous year? Solution or validation (MSS) Wisual verification and must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets required in the protection of the pro		Visual verification and related documentation (maintenance log)		4	1.2 Is the surface of the MSS cleaned with a suitable disinfectant at the beginning and end of each manipulation?
resultion (MSS) Yes No Partial Means of verification Observations Visual verification and related documentation MSS not yet operational	implete protection, biological safety cabinets requ	proper operation and con	sms. To ensure	agious organis	Norm: A biosafety cabinet must be used to prevent exposure to aerosols from specimens or contoperiodic maintenance and must be maintained accordingly. CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)
afety station (MSS) Yes No Partial Means of verification	nd MSS not yet operational	Visual verification and related documentation		<	1.1 Is there certification or validation during the previous year?
Yes No Partial Means of verification					1. Microbiological safety station (MSS)
		Means of verification	Partial		Controlled Points Y
-					Person (s) audited
				273	Head of laboratory:
Date:					Place: Date:



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.	ct with conta	minated are	eas, reagents or equipment. Unn	ecessary traffic should not disrupt workflow or
2.2 Biological hazard sign affixed to the laboratory door	<			ISO 15189: 5.2.7
2.2.1 Exact and up-to-date panel information:				
✓ Biosafety level				
✓ Anticipated risks (Pathogens)			View Coulding the and	<u>Unione</u>
✓ Researcher in charge	<		visual verification and	
N° to call in case of emergency (day and night):			(display)	
2.2.2 Panel readable and in good condition?	<			
2.3 Are all doors constantly closed?	4			P3 doors Open
3. Decontamination		116770		1 access obes
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 beginning and end of each work cycle. All accidental spills must be immediately controlled and disinfected work surfaces.	disinfectant nfected work		sed. At a minimum, all benches	used. At a minimum, all benches and work surfaces must be disinfected at the
SOP CERMEL: Cleaning and disinfection of surfaces (L-ML-039-V01-FR)				ISO 15189: 5.2.10; ISO 15190 :13
3.2 Is the laboratory supervisor notified if infectious material is widespread or involved in an accident?	<	A STATE OF THE STA	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			Visual verification and	
spilled?			(maintenance log)	
Plans de travail: Work plans must be decontaminated if they have been contaminated with potentially dangerous products and at the end	oducts and	at the end o	of the working day.	
CERMEL SOP: Cleaning of CERMEL Facilities and Laboratories (L-G-040-V02-EN)				WHO Biosafety Manual: Laboratory Design page 12
4. Handling of contaminated waste				
4.1 Good use of contaminated waste containers?		4	Visual verification	Waste are autoclaved but no bins available
4.2 No bins filled up to the brim?			Visual verification	NA: no bins
4.3 I rash bins properly labelled and closed?			Visual verification	NA: no bins



nctional.	nethods) should be available and fur	r acceptable eye washing m	Norm: Hand washing stations should be designed and equipped and eyewash stations (or other acceptable eye washing methods) should be available and functional.
	Visual verification	<	7.1 Are sinks installed near the exit of the laboratory?
			7. Convenience
es not spill, in accordance with national or WHO Biosafety Manual: pages 12 and 77	container containing the sample do	should be used so that the o	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
	Visual verification and related documentation (Biosafety Manual, SOP)	•	6.2 Infectious specimens are transported out of PSM in approved containers in accordance with the transport regulations for this type of product
WHO Biosafety Manual: Procedure page 11			Aerosol production: All techniques used must minimize the formation of aerosols and droplets.
NA	Visual verification of practices		6.1 Are auto-disable or disposable syringes used for work on infectious agents?
ISO 15190: 5.1	וכנווטמז/ זווטמומ מב מימווממוכ מוומ /מ	a acceptance se washing in	6. Practice
nctional	nethods) should be available and fu	er acceptable eve washing n	Hand mashing stations should be designed and penging and enwash stations for other
No display for this purpose	related documentation (tool: hand washing L-G-041-R2-V01-EN)	•	
	Visual verification and		5.5 Wash hands after removing gloves and before leaving the laboratory
tial list of the necessary items. ISO 15190: 5.1	y equipment. The list above is a par	quipped with standard safet	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.
	(Biosafety Manual)		
N/A	related documentation		5.4 Facial protection when working on infectious material outside MSS
operational	(Biosafety Manual)	*	
Gloves available but laboratory still not	Visual verification and		5.3 Wearing gloves for handling infectious biological material or contaminated equipment
			5. Individual protection
	Visual verification	*	4.5 Transport in sealed, solid and sealed containers of decontaminated material outside the laboratory, in accordance with local regulations
ISO 15190 :22			incinerated, burned in a pit or buried.
om exposed waste, infectious waste must be	fectious material. To avoid injury fr	taminate any notentially in	Norm: Infectious waste and sharps recentacles must be autoclased prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be
Jacobaye available in the 1901.	related documentation (Waste management)	•	4.4 Cipbs alia otilei wastes subject to regulation bioberly necontalimated between ansbosan
Autoclave available in the room	Visual verification and		1 A Drawn and other waster such in the remilation property dependent batery defended?



Table 3. Containment laboratory -BSL3

			630		
Place: Date:					
Head of laboratory:					
Controlled Points	Yes	No.	Partial	Moans of Vorification	Okamati
Overview:			. ci ciai	INICALIS OF ACTURACION	Observations
Containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 micrographisms and high volumes or consentrations of Biol. Common in the containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 micrographisms and high volumes or consentrations of Biol. Common in the containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 micrographisms and high volumes or consentrations of Biol. Common in the containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 micrographisms and high volumes or consentrations of Biol. Common in the containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 micrographisms and bloom in the containment and the containment of the containmen	vina risk aroun 3	microorgan	isms and high	volumes or concentrations of Bi-L	
susceptible to handling. to cause the diffusion of aerosols.	9	000	ons and mgn	אטומווופז טו כטווכפונוומנוטווז טן אוצא טוט	oup z microorganisms that are more
1. Laboratory design					wild biosujety Manaat, page 22
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?	s? <			Visual verification	Door not operational on the day of the audit

Design and layout of the laboratory:

2.1. Regulated ventilation system to control the direction of air circulation

4

Visual verification (manometer)

Non-operational ventilation system on the day of the audit

Non-operational ventilation system on the day of the audit

Visual verification

Visual verification

day of the audit

1.3. Are gaskets installed or can be installed at all crossings for laboratory

decontamination?

Room air not recycled and evacuated from occupied areas

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

personnel can ensure that the airflow is always correctly directed 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

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

o. Illuividual 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 washhasin in the room

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

R

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.

Prote type: aprons, gowns, lab coats, cleaning suits, overalls, headdresses and, where appropriate, shoe covers and special shoes.

WHO Biosajety Imanual, puge 22	
he forearms.	gular lab coats that button in front are not suitable, as well as sleeves that do not fully cover the forearms.

5.1. Wearing respiratory protection by all laboratory personnel when aerosols 4.1. Wearing double gloves for working with infectious material and Respiratory protection equipment or worktops that may be contaminated Visual verification of practices N / A non-operational laboratory N95 masks available

Code of good practice

6.1. Staff warned of specific risks related to the agent or infectious agents

Practice

Wearing a respirator may be necessary for some handling or when working on animals carrying certain pathogens are not safely contained in a MSS Visual verification of practices WHO Biosafety Manual, page 22

Visual verification of practices

Manual not available

and related documentation

it must be reviewed and updated at least once a year by the laboratory management. 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, (biosecurity manual, display)

6.3. Autoclaving of all waste before disposal 6.2. Annual updates to staff or additional training if changes are made to certain techniques assessment sheet, training plan) Related documentation (skills Visual verification of practices and related documentation (Biosafety Manual, Autoclave available in the room ISO 15190: 7.4

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. 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 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

ISO 15190 :22

7.1. Staff warned of specific risks related to the agent or infectious agents Health surveillance and related documentation Visual verification of practices (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.
- 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. 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 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

WHO Biosafety Manual, page 26

Auditor's Name & Signature:	Auditor's Name & Signature: Holder leader Deuguele Dom
Auditor's Name & Signature:	Auditor's Name & Signature: KNINM GANZI SOUNDA Soudeth
nd Date of control30 ^{+h}	End Date of control 30th April 2018