

Appendix 8

Assess form template for the certificate for standard biosafety level II laboratory

(Issued together with Circular No.29/2012/TT-BYT dated December 4th, 2012 by Minister of Health)

..... ¹	SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness <i>...²....., date, 20....</i>
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ASSESS FORM FOR THE CERTIFICATE FOR STANDARD BIOSAFETY LEVEL II LABORATORY

I. INFORMATION ABOUT THE FACILITY WITH LABORATORIES

Name of the facility with laboratories:

Address:

Telephone:

Email (if applicable):

Fax:

Name of laboratories:

Address of laboratories:

II. PARTICIPATOR

Assess committee:

Representative of the facility with laboratories:

III. LEGAL BASE

- Based on the Law on Prevention and Control of Infectious Diseases, dated November 21, 2007;
- Based on Paragraph 5 of Article 12 of Decree No. 92/2010/ND-CP dated August 30, 2012 by Government about implementation of the Law on Prevention and Control of Infectious Diseases for ensuring biosafety in the laboratory;
- Other related documents....

IV. ASSESS CONTENTS

Administrative document

Content	Yes	No	Note
Number of document			
Proposal form for the issue of the certificate for standard biosafety laboratory			
1. Space diagram			
- Laboratory acreage			
- Doors system			
- Windows system			
- Electric system			
- Water system			
- Fire prevention and fighting system			
- Waste control system			

2. List of equipment of the laboratory			
3. List of personnel of the laboratory			
4. Degree, certificate of the person in charge and staff of the laboratory			
5. Document of establishment and operation of the laboratory			
6. Other documents			Detail on other documents for reference

Assess content

Assess content	Document		Performance	Assessment at the laboratory		
	Yes	No		Conform	Non-conform	Note
A. Laboratory facilities						
1. Laboratory - Separate with other laboratories - Minimum acreage is 20 m ² <i>(Laboratory design is retained as document form)</i>						
2. Doors and windows system						
- Doors: Molds, handles, safety lock; door made of wood, synthetic material or metal combined with glass. - There are biohazard signs follow regulation on doors of the laboratory - Windows: Molds, safety handle; door made of wood, synthetic material or metal combined with clear or cloudy glass in order to have natural lighting. <i>(Windows and doors follow the design, describe in the document for the material)</i>						
3. Floor, walls and ceilings						
- Floors: + No difference in reinforcement, no mold ensuring flat, smooth, non-slip, chemical resistant, waterproof and easy to wash; + In the sterile lab, media or sample preparation have to have water collecting place when washing; + Intersection of floors with walls ensures easy to clean, anti-condensation. - Walls: Smooth, easy to clean, waterproof and resistant to chemicals used in the laboratory. - Ceiling: flat, smooth, waterproof and possible for the installation of the equipment (lighting, fire prevention, fire fighting, air conditioning, and other equipment).						
4. The working bench surface Waterproof, resistant to the antiseptic solution, acids, alkalis, organic solvents, and heat. <i>(Document that describes the material of the table – record in the document, proof related to material of the table)</i>	Y					
5. Lavabo, emergency eyewash equipment, first-aid box	Y					

Assess content	Document		Performance	Assessment at the laboratory		
	Yes	No		Conform	Non-conform	Note
<p>6. Lighting</p> <ul style="list-style-type: none"> - In the test area with a minimum of 400 lux illumination; - Cleaning, sterilization, media and sample preparation, bathing and dressing area with a minimum of 250 lux illumination; - Administrative and auxiliary area a minimum of 140 lux illumination; 	Y					
<p>7. Electric system:</p> <ul style="list-style-type: none"> - Stable source of power - Wiring and control equipment, power supply to ensure safe and appropriate technical parameters (capacity, quality...) - There is an overload protection system - Grounding the whole system - Sockets have higher background than the floors at least 40cm, not near the tap <p><i>(Document related to the electric system, electric providing contract, electric design)</i></p>						
<p>8. Area with UV, laser, radiation, toxins must have corresponding signs <i>(signs template, position to put signs)</i></p>	Y					
<p>9. Clean water system <i>(Clean water system map, proof that laboratory have clean water for the test, valve for preventing backflow direction flow)</i></p>						
<p>10. Fire prevention, firefighting equipment <i>(List of fire prevention, fire fighting equipment; check record for fire prevention and fighting)</i></p>						
<p>11. Waste management system meets the national technical regulation about the environment before putting into the general waste area <i>(Map of the waste system, the result of the evaluation of water quality before put into the general waste area)</i></p>	Y					
B. Laboratory equipment						
<p>1. Equipment needs to be appropriate with techniques and micro-organism being tested <i>(List of the experiment conducted. List of equipment of each test, test result, test procedure)</i></p>	Y					
<p>2. Waste containers meet the standard for every waste <i>(List of waste containers, waste containers position)</i></p>	Y					
<p>3. Biosafety cabinet level II <i>(Position, name, type, manufacturer, profile, operation of the cabinet, standard evaluation and examination of the cabinet. Result of supervising and examining microorganism in the cabinet)</i></p>	Y					
<p>4. Autoclave in the laboratory <i>(Position, name, type, manufacturer, profile, operation of the cabinet, standard evaluation and examination of the cabinet, using diary)</i></p>	Y					

Assess content	Document		Performance	Assessment at the laboratory		
	Yes	No		Conform	Non-conform	Note
<p>5. Personal protective equipment need to be appropriate with test type being conducted in the biosafety level II laboratory</p> <p><i>(List of PPE follow Regulation No 205/2002/QD-BLDTBXH, 2002 by Ministry of Labor, War Invalids, & Social Welfare)</i></p> <ul style="list-style-type: none"> - White clothes - White hat or cover hair hat - Rubber gloves - Plastic shoes - Rubber boots - Face mask - Apron for protecting from specific chemical⁽¹⁾ - Goggles for protecting from dust and specific chemical⁽¹⁾ - Soap <p><i>(1):Exclude if already in the uniform</i></p>	Y					
C. Laboratory personnel						
<p>1. Number of employees: at lease two employees</p> <p>2. Level of employees:</p> <ul style="list-style-type: none"> - Have degree or certificate that is appropriate with the test and certificate of biosafety level II training from authorized domestic or foreign facilities issued - Excel in experimental manipulation and test <p><i>(List of employees, certificate about test technique and biosafety, laboratory experience)</i></p>	Y					
D. Regulation on practice						
<p>1. Management and administration</p> <ul style="list-style-type: none"> - Facility with laboratories has the person in charge about biosafety - Regulation on reporting - Education and training plan for employees - Regulation on retaining documents <p><i>(Decision for assigning the person in charge of biosafety from the head of the facility, regulation on reporting to the head of the facility, regulation on document retain, test result, education and training, plan for incident prevention and solution)</i></p>						

Assess content	Document		Performance	Assessment at the laboratory		
	Yes	No		Conform	Non-conform	Note
<p>2. Practice</p> <ul style="list-style-type: none"> - Regulation on enter and exit the laboratory and access control procedure. - There are and compliance with test procedure - Decontamination and waste control - Incident fighting procedure - Evaluate the risk of biosafety problems happen in the laboratory - Make a plan for preventing and managing biosafety problems <p><i>(There are adequate regulation and be approved by the head, established and approved by the head; implement the approved plan)</i></p>						
<p>3. Health and medicine supervise</p> <p>Health document of the employees follow the regulation (health check before starting to work at the laboratory and annually)</p> <p><i>(Follow the circular No. 19/2011/TT-BYT, dated June 6, 2011 by Minister of Health about Guide on managing health, hygiene for employees and occupational diseases:</i></p> <ul style="list-style-type: none"> - Health certificate - Health document - Periodic health check 						

V. CONCLUSION AND SUGGESTION

Conclusion:

Suggestion (if applicable):

Objection to the conclusion and suggestion of the assess committee (if applicable):

<p>Assess committee <i>(signs and full name of each member)</i></p>	<p>Representative of the facility with laboratories <i>(sign and seal)</i></p>
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(Endnotes)

- 1 Name of assess organization
- 2 Place