

Biosafety and Security

6. Biosafety and Biosecurity

Questions	Responses	Documents Required
contextuel Questions: N/A		
Technical Questions:		
P.6.1 Whole-of-government biosafety and biosecurity system is in place for human, animal, and agriculture facilities		
1. Actively monitoring and developing an updated record and inventory of pathogens within facilities that store or process dangerous pathogens and toxins.		
a. Does the country have in place an updated record of where and in which facilities dangerous pathogens and toxins are housed? i. Have collections of pathogens and toxins been identified?	Thailand have been implemented Pathogen and Animal Toxin Act Since B.E. 2525 (1982) and update in B.E. 2558 (2015) for biosecurity and legislation of human and animal laboratories through out the country. By law, an update record and inventory of pathogen have been monitoring by Pathogen and Animal Toxin Act B.E. 2558 (2015), Department of Medical Sciences, Ministry of Public health. Laboratories shall reported to Department of Medical Sciences Department of Medical Sciences every 3 months and renewal license every year.	-Pathogen and Animal Toxin Act B.E. 2525 (1982) http://www.vertic.org/media/National%20Legislation/Thailand/TH_Pathogen_and_Animal_Toxins_Act_amended.pdf - Pathogen and Animal Toxin Act B.E. 2558 (2015) http://www.krisdika.go.th/wps/wcm/connect/0dc15d80402938228491944efdad0a77/PATHOGENS+AND+ANIMAL+TOXINS+ACT%2C+B.E.+2558+(2015).pdf?MOD=AJPERES&CACHEID=0dc15d80402938228491944efdad0a77
Animal	- There are pathogen collecting system in deep freezers and liquid nitrogen in laboratories which produce that pathogens under biosafety and biosecurity of National institute of animal	- Pathogen and Animal Toxin Act B.E. 2558 (2015) - Inventory system of virology section, bacteriology section, parasitology section, immunology section and leptospirosis center of

Questions	Responses	Documents Required
	health (NIAH) using inventory system compose of log books and computerization.	NIAH
2. Implementing enacted comprehensive national biosafety and biosecurity legislation.		
a. Does the country have biosecurity legislation and/or regulations in place? Are they being implemented?	Thailand have been implement Pathogen and Animal Toxin Act Since B.E. 2525 (1982) and update in B.E. 2558 (2015) for biosecurity and legislation of human and animal laboratories through out the country. Safety, occupational health and working environment Act B.E. 2554 (2011) has an exception for government agencies, but Cabinet resolution requires government agencies to provide worker safety not less than the standards Safety, occupational health and working environment	1.Pathogen and Animal Toxin Act B.E. 2525 (1982) 2.Pathogen and Animal Toxin Act B.E. 2558 (2015) 3. Safety, occupational health and working environment Act B.E. 2554 (2011) http://oshthai.org/images/News_images/pdf/OSH%20ACT.pdf 4. National Health Act BE 2550 (2007) http://www.thailawforum.com/laws/National%20Health%20Act_2007.pdf
Animal	- NIAH updates and manages pathogen declaration under Pathogen and Animal Toxin Act B.E. 2558 (2015) by coordinating among laboratory networks (Regional Veterinary Research and Development Centers, RVRDCs) send the pathogen information lists to Department of Medical Sciences. - NIAH provide Laboratory biosafety and	Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
	biosecurity training course for NIAH staff and laboratory networks staff once a year.	
b. Does the country have biosafety legislation and/or regulations in place? Are they being implemented?	The answer is the same as 2a and announcement of the New Act will be finish in February 2018	- National Health Act B.E 2545 (2002) - Control Army Act BE 2551 (2008) - Biological Substances, Chemicals and Explosives and various protective devices. - Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	- NIAH established biosafety and biosecurity guidelines for NIAH and laboratory network. - NIAH and laboratory network are ISO/IEC 17025 accredited by Bureau of Laboratory Quality Standard (BLQS), Department of Medical Sciences.	-Laboratory biosafety manual (Translation from WHO guideline): http://niah.dld.go.th/th/files/biosafety/manual_LabBiosafety.pdf -Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety : http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf -ISO/IEC 17025:2005 certification
c. Please provide a copy of the country's national biosecurity legislation, regulations or frameworks, and a copy of the country's biosafety		1.Pathogen and Animal Toxin Act B.E. 2525 (1982) 2.Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
legislation, regulations or frameworks.		
i. Please describe how this information is shared with laboratories at subnational levels within the country.	The National Public Health Laboratory is the Department of Medical Sciences (DMSc). Conduct training for laboratories network throughout the country via Regional Medical Sciences Center (RMSc.) in emergency situations. Then, the Regional level trainers will be train and practical at provincial and hospital level.	
Animal	- NIAH updates and manages pathogen declaration under Pathogen and Animal Toxin Act 2558 B.E. by coordinating among laboratory network and send the pathogen information lists to Department of Medical Sciences. - NIAH provide Laboratory biosafety and biosecurity training course for NIAH staff and laboratory networks (RVRDCs) staff once a year.	Action plan
ii. Are regulations and/or guidelines for biosecurity followed by laboratories within the country? What about for biosafety?	The answer the same as 1a 1. By law, an update record and inventory of pathogen have been monitoring by Pathogen and Animal Toxin Act B.E. 2558 (2015), Department of Medical Sciences, Laboratory shall reported every 3 months and renewal license at December of every year. 2. Each Level of medical laboratory have been audit/inspect/Accreditation with hospital accreditation (HA), Laboratory Accreditation	-Certification of ISO 15189 & ISO 15190 -Certification of ISO/IEC 17025 -Certification of ISO 9001 -Quality standards in health laboratories implementation in Thailand (http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_quality_standards_in_health_laboratories_thailand.pdf?ua=1)

Questions	Responses	Documents Required
	(LA) or ISO 15189 and ISO15190.	
Animal	- NIAH established biosafety and biosecurity guidelines for NIAH and laboratory network. - NIAH and laboratory network are ISO/IEC 17025 accredited by Bureau of Laboratory Quality Standard, Department of Medical Sciences	-Laboratory biosafety manual (Translation from WHO guideline): http://niah.dld.go.th/th/files/biosafety/manual_LabBiosafety.pdf -Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety: http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf -ISO/IEC 17025:2005 certification
iii. Describe biosecurity monitoring activities. Describe biosafety monitoring activities	The answer the same as 1a -By law, an update record and inventory of pathogen have been monitoring by Pathogen and Animal Toxin Act B.E. 2558 (2015), Department of Medical Sciences, Laboratory shall reported every 3 months and renewal license at December of every year. -Each Level of medical laboratory have been audit/inspect/Accreditation with Hospital Accreditation (HA), Laboratory Accreditation (LA), Ministry of Public Health (MOPH standard) or ISO 15189 and ISO15190.	-Pathogen and Animal Toxin Act B.E. 2558 (2015) -Hospital Accreditation (HA) -Laboratory Accreditation (LA) -Ministry of Public Health (MOPH standard) -ISO 15189 -ISO15190
Animal	- There is biosafety and biosecurity internal audit at NIAH once a year by IBC of NIAH	- Biosafety and biosecurity internal audit form of NIAH :

Questions	Responses	Documents Required
	-There was training on FAO laboratory mapping tool (FAO-LMT) for NIAH and laboratory network staff which is very useful for performing biosafety and biosecurity self-assessment. -	http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=10122:-1-3-&catid=49:biosafetybiosecuritylab&Itemid=311 - FAO-LMT: http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=1283:faoblmtfaolmt&catid=49:biosafetybiosecuritylab&Itemid=311 - LMT (laboratory mapping tools)
iv. Has a third party assessed biosecurity at national laboratory facilities? What about biosafety? 1. When? 2. Have the recommendations from that biosecurity assessment been put into place? What about for biosafety?	WHO: An Assessment to Support Strengthening Laboratory Capacity for Emerging and Dangerous Pathogens in Thailand 1. When 13-17 June 2016 2. Have the recommendations from that biosecurity assessment been put into place? Yes : Certification of BSL-3 What about for biosafety? No recommendation	Report of the WHO Emerging and Dangerous Pathogens Laboratory Network (EDPLN) visit to National Institute of Health, Thailand. 13-17 June 2016 -Attached Report from WHO
Animal	- FAO have been Assess Animal laboratory by LMT (laboratory mapping tools) in 2012 and 2014. The expert have been comment on biosafety and biosecurity -There were certification of Biosafety Cabinet (BSC) by FAO in 2012 and 2014.	- Mission report on biosafety risk assessment at NIAH by Dr. Stuart Blacksell (FAO) during 21-24 JUNE 2012: http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=10132:external-audit-by-fao-during-2012-2014&catid=49:biosafetybiosecuritylab&Itemid=311

Questions	Responses	Documents Required
	-The first national inception workshop and training on the use of the core LMT and its safety module took place in Thailand in February 2016 with participation from the national network of Thai veterinary laboratories.	- Mission report on biosafety risk assessment at NIAH by Dr. Stuart Blacksell (FAO) on 8 April 2014: http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=10132:external-audit-by-fao-during-2012-2014&catid=49:biosafetybiosecuritylab&Itemid=311 - BSC testing by FAO during 21-24 JUNE 2012: http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=10132:external-audit-by-fao-during-2012-2014&catid=49:biosafetybiosecuritylab&Itemid=311 - BSC testing by FAO during on 8 April 2014: http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=10132:external-audit-by-fao-during-2012-2014&catid=49:biosafetybiosecuritylab&Itemid=311 -FCC-EMPRES Information Sheets : STRENGTHENING VETERINARY DIAGNOSTIC CAPACITIES: THE FAO LABORATORY MAPPING TOOL http://www.fao.org/3/a-i5439e.pdf

Questions	Responses	Documents Required
v. What type of laboratory requires a licence in the country?	Following by law, Pathogen and Animal Toxin Act B.E. 2558 (2015) - A private laboratories shall have a license to possess, produce, distribute and dispense before proceeding or workable and shall submit possession report to Department of Medical Sciences. -All laboratories that import and export germs into the Kingdom must have a license, possession, production, distribution, distribution of germs. It will be possible to pass the customs clearance for importing and exporting germs. -All public and private entities producing, selling, importing, exporting or importing via pathogens or biological agents that cause disease in humans, animals, livestock and vectors.	Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	- ISO/IEC 17025 accredited by Bureau of Laboratory Quality Standard, Department of Medical Sciences.	ISO/IEC 17025
vi. Are there common licence conditions/safety and security requirements for all licensed labs? If so, what are they?	Following by law, Pathogen and Animal Toxin Act B.E. 2558 (2015 Pathogen and Animal Toxin Act B.E. 2558 (2015) - annoucemencc of the New Act will be promulgate (finish) with in February 2018 -There are various criteria such as buildings, facilities, safety equipment. And the person in	Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
	charge of the operation, etc., details in accordance with the Ministerial Regulations prescribing the rules, procedures and conditions for applying for and granting of production licenses. Selling, importing and exporting or transmit germs and toxins from animals -Private agencies shall have a license to possess, produce, distribute, distribute and transmit pathogens and toxins before proceeding. Public agencies do not need a license anyway shall report on activity occupation, production, distribution, distribution and transmission of pathogens and toxins from animals to the Office of the Animal Health and Veterinary Services Act every three months. -License issued by the Department of Medical Sciences only. Government agencies waived the license but must be note.	
Animal	Same as human health. -ISO/IEC 17025 accredited by Bureau of Laboratory Quality Standard (BLQS), Department of Medical Sciences.	Pathogen and Animal Toxin Act B.E. 2558 (2015)
vii. How is laboratory licensing monitored within the country?	-By law, an update record and inventory of pathogen have been monitoring by Pathogen and Animal Toxin Act B.E. 2558 (2015), Department of Medical Sciences, Laboratory	- Pathogen and Animal Toxin Act B.E. 2558 (2015) - ISO 15189 - ISO 15190

Questions	Responses	Documents Required
	shall reported every 3 months and renewal license at December of every year. -Inspection by legal staffs following Pathogen and Animal Toxin Act B.E. 2558 (2015) once a year	
Animal	-NIAH and laboratory network are assessed by Bureau of Laboratory Quality Standard, Department of Medical Sciences every year.	ISO/IEC 17025
viii. Is there adequate availability of funding to support biosecurity programs/initiatives and their oversight and enforcement at the ministry level? What about for biosafety?	1. The support budget is sufficient. 2. Supervision and enforcement at ministerial level 3. Procurement of the infection applicants must have a biosafety training certificate.	Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	1. The support budget is sufficient. 2. Supervision and enforcement at ministerial level 3. Procurement of the infection applicants must have a biosafety training certificate	Pathogen and Animal Toxin Act B.E. 2558 (2015)
ix. Is there a mechanism for biosecurity oversight of dual use research and responsible code of conduct for scientists? This may include a biosafety committee or other review committee	-The dual use of research and code of conduct is currently under development (deadline February 2017) -The Pathogen and Animal Toxin Act B.E. 2558 (2015) requires to establish an Institution Biosafety committee (IBC) to review the	Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
	suitability of routine works and research that meets the biosafety and biosecurity requirements.	
Animal	-The dual use of research and code of conduct is currently under development (deadline February 2017) -The Pathogen and Animal Toxin Act B.E. 2558 (2015) requires to establish an Institution Biosafety committee (IBC) to review the suitability of routine works and research that meets the biosafety and biosecurity requirements.	Pathogen and Animal Toxin Act B.E. 2558 (2015)
3. Implementing laboratory licensing and pathogen control measures including requirements for physical containment and operational practices and containment and failure reporting systems.		
a. Physical Security: are appropriate security measures in place to minimize potential inappropriate removal or release of biological agents (e.g. theft, earthquake, and flood)?	The National Committee on Pathogen and Animal Toxin Act is considering the drafting of the Ministry of Public Health's Building Regulations : regulations, and procedures for working with organisms and toxins from Animals must comply with the notification. - Medical Laboratory which work with pathogen	ISO 15190

Questions	Responses	Documents Required
	level 2 shall consider general design requirement and laboratory security (door lock, key card and fingerprint scan) for ISO 15190 (medical laboratory- requirements for safety)	
Animal	-There are biosecurity measures at NIAH using key card system and keeping pathogens in refrigerators that have key-locked and limit only some responsible staff to access.	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety: http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf
b. Information Security: is access to sensitive information (e.g. inventory of agents and toxins) controlled by adequate policies and procedures?	Follow SOP : quality system in aspects of information security and also The Official Information Act B.E.2540 (1997). -Using key card to entrance the door and keep valuable pathogens and specimens in key-locked refrigerator and limited responsible staff.	ISO 15189 The Official Information Act B.E.2540 (1997)
Animal	-There are biosecurity measures at NIAH using key card system and keeping pathogens in refrigerators that have key-locked and limit only some responsible staff to access.	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety: http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf - ISO/IEC 17025

Questions	Responses	Documents Required
c. Transportation Security: are procedures for a safe and secure transport of culture, specimens, samples and other contaminated materials established and followed?	The National Committee on Pathogen and Animal Toxin Act is drafting a regulation on the Transport of Toxins and pathogen. -Laboratories are familiar to work with 3 packaging system for infectious substance transportation when outbreak of bird flu in B.E.2547 (2004) -Medical and animal laboratory have the manual of collecting and transportation.	Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	-There is work instruction for laboratory biosafety established by institutional biosafety committee (IBC).	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety: http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf
d. Personnel Security: is there a mechanism to determine which personnel are authorized to access pathogens of security concern?	-The National Committee on Pathogen and Animal Toxin Act is drafting the regulation of Building and related procedures. -Using key card to entrance the door and keep valuable pathogens and specimens in key-locked refrigerator and limited responsible staff.	Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
Animal	-There are biosecurity measures in NIAH by using key card system and keeping pathogens in refrigerators that have key-locked and limit only some responsible staff to access.	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf -Work instruction for laboratory biosafety: http://niah.dld.go.th/th/files/biosafety/Biosafety_procedure_2012_07.pdf
e. Biosafety and biosecurity practices at facilities housing or working with dangerous pathogens:		
i. Are site-specific biosafety and biosecurity management programs and supporting documents (manuals, SOPs, job aides, records) available to include biosafety, biosecurity, incident response and emergency plans (e.g. in case of explosion, fire, flood, worker exposure, accident or illness, major spillage)?	-There are SOPs to comply with ISO 15189 and ISO 15190 - The National Committee on Pathogen and Animal Toxin Act is drafting the regulation of building regulations, regulations and procedures to working with pathogens (By Law will be released before February /2017)	-ISO 15189 -ISO 15190
Animal	-There are institutional manual, guideline and records.	-Laboratory biosafety manual (Translation from WHO guideline): http://niah.dld.go.th/th/files/biosafety/manual_LabBiosafety.pdf -Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_

Questions	Responses	Documents Required
ii. Are roles and responsibilities related to biosafety and biosecurity management defined and documented (biosafety officer, security manager)?	- The institutional have Biosafety Officer and responsibility to complied with ISO - There are SOPs to complied with ISO 15189 and ISO 15190 - The National Committee on Pathogen and Animal Toxin Act is drafting the regulation of building regulations, regulations and procedures to working with pathogens (By Law will be release before February /2017)	-ISO 15189 -ISO 15190
Animal	-There are institutional appointments for institutional biosafety committee (IBC) and biosafety officer (BSO).	- IBC appointment of NIAH: http://niah.dld.go.th/th/files/biosafety/niah_order_59_81.pdf
iii. Have the biosafety and biosecurity risks been assessed and categorized?	Department of Medical Sciences (DMSc) have been organized and train Biorisk Management (BRM) for other Division of DMSc and Regional Medical Sciences center (RMSc) including hospital for 3 years (2014-this year 2016) -This workshop have show how to perform risk assessment in laboratory.	- BRM tool kits - Assessment form
Animal	-Biosafety and biosecurity risks been assessed and categorized lab staff under head of laboratories using institutional risk assessment form established by IBC.	Risk assessment form http://niah.dld.go.th/th/index.php?option=com_content&view=article&id=1271:2016-03-22-00-37-54&catid=49:biosafetybiosecuritylab&Itemid=311

Questions	Responses	Documents Required
iv. Are biosafety and biosecurity control measures described in an action plan?	Laboratory have action plan following SOP of institution and ISO requirement,	Institution SOP
Animal	Yes. There is action plan	Institutional guideline -Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_biosafety_review2010.pdf
v. Are there mechanisms to ensure that personnel is suitable and competent (e.g. best practices) in human resources management (e.g., verification of prior education and employment, periodic performance reviews), successful completion of training, mentorship programs, ability to work unsupervised)?	-Laboratory have SOP of institution and ISO requirement, -Action plan and monitoring the plan	
Animal	Yes, Quality system	On the job trainings ISO/IEC 17025
f. Is there a system in place to conduct audits of laboratory facilities?	Quality system of ISO (internal audit and External audit by Accreditation body (AB : Bureau of Laboratory Quality Standard, BLQS) once a year)	Requirement of ISO 15189

Questions	Responses	Documents Required
Animal	Quality system of ISO (internal audit and External audit by Accreditation body (AB : Bureau of Laboratory Quality Standard , BLQS) once a year)	ISO/IEC 17025
i. If so, are audits performed regularly?	Once a year	ISO 15189
Animal	Once a year	ISO/IEC 17025
ii. What organization conducts these audits? Within the government or external?	-Internal audit by institutional staffs -External audit by Accreditation body : BLQS, DMSc -Inspection by legal staff once a year with The Pathogen and Animal Toxin Act B.E. 2558 (2015)	- ISO 15189 -The Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	- Internal audit conducted by Institutional Biosafety Committee (IBC) - External audit by Accreditation body : BLQS, DMSc	ISO/IEC 17025
iii. Which types of laboratories are subject to these audits?	Inspection by legal staff once a year in the laboratory who have Risk group 3	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	-Diagnostic laboratories. Veterinary laboratories of Department of Livestock Development	ISO/IEC 17025

Questions	Responses	Documents Required
g. Do laboratories have appropriate ISO accreditation? If so, which ISO accreditations do the facilities have?	ISO 15189 ISO 15190 ISO/IEC 17025 ISO 17043 AAALAC	NIH have been Accreditation of ISO since 2006 Attached Certification ISO - Certification ISO 15189-2012-NIH - Certification ISO 17025-2012-NIH Certification ISO 17043-2012-NIH Certification AAALAC-2012-NIH
Animal	- ISO/IEC 17025:2005 - ISO 9001:2008	NIAH have been Accreditation of ISO since 2008 Attached Certification of ISO 17025
h. Do any of the national laboratories have other relevant classifications? (i.e. WHO Collaborating Centre, OIE Reference Laboratory, FAO Reference Laboratory/Collaborating Centre)	Thai-NIH : WHO RRL, WHO CC - WHO Polio Regional Reference Laboratory in South-East Asia Region. (Since 1993) - WHO Regional Reference Laboratory for the Measle/Rubella Laboratory Network in South-East Asia Region. (Since 2004) - WHO Regional Influenza Reference Laboratory In South-East Asia Region. (Since 2010) - WHO Collaborating Center for Antimicrobial Resistance Surveillance and Training (Since 2014, THA-71) - WHO Accreditation as National HIV-1 Drug Resistance Genotyping Laboratory (Since 2009)	- Attached P6.1.3 WHO-RRL-CC-NIH - Attached P6.1.3 Nominate RRI Thailand-WHO Measle RRL-SEAR - Attached P6.1.3 WHO CC Antimicrobial Resistance-19March 2014
Animal	- OIE Regional Reference Laboratory for Foot	- Attached P6.1.3 OIE FMD

Questions	Responses	Documents Required
	and Mouth Disease in Southeast Asia - OIE Reference Laboratory for Brucellosis	-Attached P6.1.3 Thailand OIE Ref Brucellosis
4. Completed consolidating dangerous pathogens and toxins into a minimum number of facilities.		
a. Has the country considered consolidating the locations for dangerous pathogens and toxins and, if so, has that been implemented?	Dangerous pathogen (Risk group 2-4) shall be report to Department of Medical Sciences every 3 months.	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	- Dangerous pathogens have been collected on sites of laboratories who produce the pathogens and report to Department of Medical Sciences every 3 months	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
i. If not, will consolidation be considered?	-	-
Animal	-	-
b. Have collections of dangerous pathogens been consolidated into a minimum number of facilities?	No, just recommend that laboratory must have facility and contain with biosafety and biosecurity and number of each pathogens shall report to DMSc every 3 months	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	No, just recommend that laboratory must have facility and contain with biosafety and biosecurity and number of each pathogens shall report to DMSc every 3 months	The Pathogen and Animal Toxin Act B.E. 2558 (2015)

Questions	Responses	Documents Required
5. Employing diagnostics that preclude culturing dangerous pathogens.		
a. Does the country utilize diagnostic tests that eliminate the need for culturing dangerous pathogens?	Production and procurement of appropriate testing kits for certain pathogens are underway. Reference laboratory are use Conventional method or standard method eg. <i>B. pseudomallei</i> , Leptospirosis, TB, Flu	
Animal	NIAH utilize some diagnostic techniques that preclude culturing dangerous pathogens	PCR, ELISA, Immuno-histochemistry and In-situ Hybridization
6. Implementing oversight and enforcement mechanism, and ministries have made available adequate funding to support the comprehensive national biosafety and biosecurity system.		
a. Are there mechanisms for oversight, enforcement and attribution for biosecurity legislation, regulations and/or guidelines? What about for biosafety?	There is a system of supervision by the official staff include both biosafety & biosecurity.	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
Animal	There is a system of supervision by the official staff include both biosafety & biosecurity.	The Pathogen and Animal Toxin Act B.E. 2558 (2015)
b. Does the country have funding for	Funding by Thai government.	Government budget

Questions	Responses	Documents Required
these activities? Is the funding source sustainable?	The funding is sustainable.	
Animal	Funding by Thai government. The funding is sustainable.	Government budget
P.6.2 Biosafety and biosecurity training and practices		
1. Country has a training program in place at all facilities housing or working with dangerous pathogens and toxins.		
a. Is biosecurity training in place across all facilities housing or working with dangerous pathogens? What about biosafety training?	Biosafety and biosecurity training course organized by Department of Medical Sciences and another sectors such as The Biosafety Association (Thailand) : BSAT and other Academic sector.	Attached BSAT program
Animal	There is training on biosafety and biosecurity at NIAH once a year and another sectors such as The Biosafety Association (Thailand) : BSAT and other Academic sector.	Attached P6.2.1 a and P6.2.1 b
b. Is a common curriculum used for biosecurity training across all facilities housing or working with dangerous	- Through Biorisk management (BRM) course by Department of Medical Sciences to the government hospitals and many units	

Questions	Responses	Documents Required
pathogens? What about for biosafety?	concerned. - Regulations are in process.	
Animal	The Biosafety Association (Thailand) : BSAT	
2. Training on biosafety and biosecurity has been provided to staff at all facilities that maintain or work with dangerous pathogens and toxins.		
a. Does your country conduct needs assessments for biosafety and biosecurity trainings? How often?	Once a year as recommendation of IHR and quality system	
Animal	Once a year as recommendation of quality system	Attached P6.2.2 Training Investigation
b. How often is staff trained on biosecurity procedures? What about biosafety?	-Staffs have been trained through workshop of Biorisk management (BRM) once a year. This workshop have been organized for 3 years continuously. -DMSc have also workshop train to the trainer of Biorisk Management. -Staffs also trained by the HR plan	

Questions	Responses	Documents Required
Animal	Once a year	
c. How often is staff tested or exercised on biosecurity procedures? What about biosafety?	- once a year - Biosecurity: based on biorisk assessment - Biosafety : based on ISO 15189/15190	
Animal	No	
d. How are these exercises monitored and assessed?	-Perform annually review of risk assessment in the laboratory then Plan-Do-Check-Act. - Perform examination and scoring of the course and certification - Competency of staffs shall assessment once a year by Quality system.	Institutional SOP
Animal	No	
e. Do these exercises include a process to document successes and areas for improvement?	Yes. testing, making suggestion and conclusion of each workshop.	
Animal	No	
f. Are there corrective action plans in place?	Follow the SOP: corrective action as Quality management requirement	
Animal	Yes, Quality system : WI	
3. Country is implementing a train-the-trainers program.		
a. Does the country have a train-the-trainer program for biosafety and biosecurity?	Through Biorisk management course (BRM) by Department of Medical Sciences (DMSc) to the Regional Medical Sciences Center (RMSc)	

Questions	Responses	Documents Required
Animal	There will be a train-the-trainer program for biosafety and biosecurity in 2017.	Attached P6.2.3 Draft NIAH training biosafety timeline 2017
4. Country has in place sustained academic training in institutions that train those who maintain or work with dangerous pathogens and toxins.		
a. Do academic institutions in the country have biosafety training programs in place for those training to work with dangerous pathogens?	Yes, in general Good microbiological practice in the University. In the Institute, shall be train all new staff before working in the laboratory.	
Animal	general biosafety	
5. Country has funding and capacity to sustain biosafety and biosecurity training.		
a. Does the country have funding for these activities? Is the funding source sustainable?	Mainly funding support annually by Thai Government budget but not enough to complete all activity so each laboratory shall priority the high risk activity.	
Animal	The funding source is sustainable by Thai government budget.	
6. Are the new facilities planned with long-term commitment of resources	Accreditation of Biosafety Level 3 (BSL-3)	

Questions	Responses	Documents Required
for operation and maintenance and formally commissioned before opening?		
Animal	Accreditation of ABSL 2, ABSL 3	
7. Can the biosafety cabinets (BSC) be serviced locally?	There are several service providers (company) for this issue. However they have to be train and pass the examination then got certification from NSF certifiers in DMSc., NIAH and AFRIM.	Workshop Biosafety cabinet for Service Providers
Animal	Yes	By institutional certifier (NSF 49)
8. Are there sufficient national resources (budget and human) to ensure proper and timely maintenance of facilities and equipment?	Partial / depends on priority setting	
Animal	There are sufficient national resources (budget and human) to ensure proper and timely maintenance of facilities and equipment.	
9. Is there induction and refresher training for all laboratory staff on biosafety and biosecurity?	Once a year	
Animal	Once a year.	
10. Is there an appropriate waste management policy?	Policies Proposed to Cabinet in 2005 • Waste separation and utilization • Share disposal facilities (Cluster)	- National Health Act. B.E.2535 (1992) - Enhancement and Conservation of National

Questions	Responses	Documents Required
	• Encourage integrated technologies and waste to energy • Private involvement for investment and operation	Environmental Quality Act. B.E.2535 (1992) http://www.wepa-db.net/policies/law/thailand/environmental_law.htm - National Health Act B.E 2545 (2002) -The Notification of the ministry of industry on Disposal of wastes or industry on Disposal of wastes or unusable materials B.E. 2548 (2005)
Animal	Yes.	Under Institutional Biosafety Committee (IBC)
11. Is there a mechanism to ensure and monitor staff competence and proper training at all laboratories?	Yes. Individual competency has been developed as requirement of International standard which they involve, including the MOPH standard.	
Animal	On the job training.	ISO/IEC 17025
12. Does each facility have sufficient PPE based upon the local risk assessment?	Yes.	ISO 15189
Animal	Yes	ISO/IEC 17025
13. Is there a framework to document, report, investigate and address any	1.National level is followed -Occupational Safety, Health and Environment	-Occupational Safety, Health and Environment Act

Questions	Responses	Documents Required
incidents and accidents at the facility and national levels?	Act B.E. 2554 (2011) - Act of prevention and mitigation B.E.2550 (2007) - Pathogen and Toxin Act B.E. 2558 (2015) 2. Institutional level is followed as various quality management such as ISO , Laboratory assurance (LA), Ministry of Public Health (MOPH) standard	B.E. 2554 (2011) http://web.krisdika.go.th/data/law/law2/%a4114/%a4114-20-2554-a0001.pdf https://www.ilo.org/dyn/natlex/docs/ELECTRONIC/89337/102609/F1657509054/THA89337.pdf - Act of prevention and mitigation B.E.2550 (2007) http://app-thca.krisdika.go.th/Naturesig/CheckSig?whichLaw=law2&folderName=%bb46&lawPath=%bb46-20-2550-a0001 -Pathogen and Toxin Act B.E. 2558 (2015) -ISO standard -LA standard -MOPH standard
Animal	Yes Report to director through IBC	Accident report form
14. Are national regulations in place and up-to-date for the transport of infectious substances (Categories A and B)?		
a. If yes, do local carriers ensure the transport of infectious substances according to the national regulations?	Not complete enforcement	
Animal	Not complete enforcement	

Questions	Responses	Documents Required
b. Do the people responsible for the shipment of specimens have access to training on infectious substance transport?	There are 40 shippers who were trained by WHO shipper training module (WHO certification). This training course organized by DMSc.	
Animal	In-country transportation	In-house biosafety and biosecurity training.
i. If yes, are these trainings in line with United Nations regulations on the transport of infectious substances?	-By WHO training module: Infectious Substances Shipping Training (Shipper's programme 2015-2016) -at least 4 of DMSc staffs were certified by WHO	WHO training module: Infectious Substances Shipping Training (Shipper's programme 2015-2016 http://www.who.int/ihr/is_shipping_training/en/
Animal	In the last few years just a few staff attended the trainings in line with United Nations regulations on the transport of infectious substances	Workshop Training at Mahidol Oxford Tropical Medicine Research Unit (MORU)
15. Do laboratory personnel have equal access to occupational/worker health services in all facilities?	Occupational Safety, Health and Environment Act B.E. 2554 (2013) have been implemented since 2015.	Occupational Safety, Health and Environment Act B.E. 2554 (2013)
Animal	Occupational Safety, Health and Environment Act B.E. 2554 (2013)	Occupational Safety, Health and Environment Act B.E. 2554 (2013)

Questions	Responses	Documents Required
16. Is there a specific vaccination policy (pre-exposure prophylaxis) for laboratory personnel (Hepatitis B and other relevant diseases)?	- Hepatitis B vaccine for staffs who work with blood, serum, body fluid or human tissue - Seasonal flu for all - Based upon documented laboratory infection risk assessment. - The selection of vaccines can be effective prevented through an active immunization programme.	ISO 15190
Animal	Yes. Seasonal flu and rabies.	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_
17. Is post-exposure prophylaxis treatment provided to laboratory workers in all facilities?	Yes.	ISO 15190
Animal	Yes. rabies.	-Laboratory biosafety manual of NIAH: http://niah.dld.go.th/th/files/manual_lab_

Key Stakeholders (List them):

❖ Thai NIH, Department of Medical Sciences, Ministry of Public Health

- Public Health Hospital over the country
- Private Hospitals
- Private Laboratories / Companies
- Regional Medical Sciences Centers (RMSC)
- Department of Disease Control (DDC)
- Bureau of Epidemiology (BOE)
- Thai FDA

❖ NIAH, Department of Live stock, Ministry of Agriculture

- Stateagency
 - 1.1 Under Department of Livestock Development
 - 1.1.1 Provincial livestock (farmer's cases through provincial livestock))
 - 1.1.2 Bureau of Animal Husbandry and Genetic Improvement
 - 1.1.3 Bureau of Livestock Standards and Certification (Meat and milk examination)
 - 1.1.4 Bureau of Biotechnology in Livestock Production
 - 1.2 Department of National Parks, Wildlife and Plants Conservation (Natural wildlife and captive wildlife)
 - 1.3 The Zoological Park Organization Under the Royal Patronage (Zoo animals)
- Private agency
 - 2.1 Private University
 - 2.2 Private farms