

ASEAN HEALTH COOPERATION CONCEPT NOTE ¹

I. PROJECT TITLE:

(Provide a concise project title that captures the essence of the proposed activity, i.e. ASEAN – Canada's GPP Project on Mitigating Biological Threats – Laboratory Capacity Development for Diagnostic EDP.

Enhancing Biosafety, Biosecurity and Bioengineering for Health Laboratories in ASEAN

II. BRIEF PROJECT DESCRIPTION-300 WORDS MAX:

(Provide a brief description of the proposed activity its objective and key activities or outputs)

During 2017-2018 fiscal years, the Department of Medical Sciences (DMSC) of MOPH, Thailand has been funded by the GPP program on Biologics and Chemical Security and UNSCR 1540 scheme for the project entitled **“Biosafety engineering and control for health laboratories in ASEAN.”** This project served as the foundation of key networking activities among ASEAN member states on improving the biosafety and bioengineering within each country and considered as one of the attempts to harmonize biosafety and biosecurity guidelines in ASEAN. The project has accomplished its preset goal by establishing ASEAN biosafety network. Through this network, the project identified key regional gaps and needs and also identified the competent candidates from each country for driving the improvement of biosafety and biosecurity. With the primary focus on extension of proper knowledge on Biosafety cabinet (BSC) technology, maintenance and certification among ASEAN member states, as this equipment serves as the primary containment for controlling biological spread in laboratory. The project organized series of workshops on basic and intermediate BSC technology and continuous evaluation on participants. After the program ended, it successfully delivered 19 participants who passed the written examination as proof of understanding on international BSC standard NSF/ANSI 49. One of the 19 proceeded to get enlisted as the NSF/ANSI 49 certifier on BSC class II basic field certification which reflects deep knowledge on BSC technology and certification. As noteworthy as the accomplishment of these 19 participants is the personal relationship among the participants that was created during these series of workshops via personal contacts and social network that helps creating a deep relationship, knowledge sharing and unity toward the ultimate goal on Biosafety and Biosecurity of ASEAN.

Therefore, in this project, we aim to expand from the primary focus of BSC technology and certification toward harmonizing the Biosafety, Biosecurity and Bioengineering of the ASEAN through series of activities which are **1) Improvement and maintaining BSC standard and enhancing Bioengineering, 2) Biorisk Management Toolkit Harmonization and 3) Set up of Regional Biorisk Management Training Centre and Thailand-Lao PDR bilateral Biorisk management training workshop.**

III. PROJECT CLASIFICATION: ASCC BLUEPRINT:

(Provide information to explain how the project activity will contribute to ASEAN's goal and relevant SDGs and targets. For this section you may refer to the first and two pages of ASEAN Health Cluster Work Programme 2016-2017)

ASCC Blueprint

¹ This concept note is based on the ASEAN Cooperation Project Proposal as of 2017 approved by the Committee of Permanent Representatives (CPR) to ASEAN

- (a) Characteristic: **This project is considered to be in line with characteristic D2: A Safer ASEAN that is able to respond to all Health-related Hazards including Biological, Chemical, and Radiological nuclear, and Emerging Threats. As the outcome of this activity is to enhance the biosafety, biosecurity and biorisk management in health laboratories in ASEAN to be ready for outbreak mitigation and response.**
- (b) Action line/strategic measures: **This project is considered to be in line with strategic measures describes in ASCC blueprint as “Strengthen health systems to be resilient in preparedness for effective response to health-related hazards, including biological, chemical, radiological-nuclear hazards and emerging threats”**

SDGs

- (c) Goal **No. 3 Ensure healthy life and promote well-being for all at all ages**
- (d) Target **3.D: Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks is the main target since this project will create a network and environment that support the preparedness toward health risk reduction and management in terms of emerging and re-emerging infectious risk. While it could also support the target 3.C in terms of development and training the healthcare workforce for biosafety, biosecurity and biorisk management.**

IV. PROPOSED COMMENCEMENT & COMPLETION DATE:

August 2018 – March 2021

V. PROPONENT’S (MINISTRY OF HEALTH) NAME AND ADDRESS & IMPLEMENTING AGENCY’S (RELEVANT DIVISION WITHIN MOH THAT WILL ORGANISE THE PROJECT ACTIVITIES) NAME AND ADDRESS :

(Kindly fill in the implementing agency if it is different from the proponent)

Ministry of Public Health, Thailand

***Implementing agency: Department of Medical Sciences 88/7 Soi Bumrasnaradur Tiwanon Rd.
Taladkwan Muang Nonthaburi 11000, THAILAND***

VI. PROPOSED BUDGET & FUNDING SOURCE:

Total Budget for the project: 848,694 USD (Please see the attached break down of budget for each activities in separate file)

VII. PROJECT JUSTIFICATION, REGIONALITY AND BENEFICIARIES – 600 WORDS MAX

(a) Current Problem

(Describe briefly the issues or problems in the region or sector that the project seeks to address. Explain what is causing these issues or problems. Your write-up has to be clearly linked to the project objective)

Biosafety and Biosecurity are key concepts in prevention and mitigation of potential risk of disease outbreak, emerging and re-emerging infectious disease. During the GHSA detect 1: strengthening national laboratory network meeting in Bangkok 2015 and 2016, Biosafety and

biosecurity is identified as gaps for human health and animal health laboratories in ASEAN and was prioritize as one of the issue that needs to be strengthen the most. In addition, during the Joint External Evaluation took place in ASEAN during 2016-2017, Thailand, Lao PDR and Vietnam are among 26 countries that join this evaluation. For Vietnam and Lao PDR, the score for biosafety and biosecurity were adequate and suggest that it could be improved more. For Thailand, it is clearly stated in the WHO mission report that even though the overall scores are acceptable, the inter-organization collaboration especially on the preparedness for emergency can be further improved. This also suggests sharing of staff and trainings that include staffs from different agency shall improve the inter-organization cooperation and leads to efficient response against emergency or outbreak.

Biosafety engineering controls are critically important equipment in health laboratories dealing with infectious substances. Biological Safety Cabinet (BSC) is the primary engineering control for the minimization of exposure to potentially infectious materials. BSC combines directional air flow and high efficiency particulate air (HEPA) filters to protect researchers and the environment from aerosolized microorganisms. Air enters the cabinet through the face (where the investigator sits), preventing contaminants generated at the work surface from entering the laboratory. Air discharged from the cabinet first passes through a HEPA filter, removing 99.99% of particles with a diameter of 0.3 microns; smaller or larger particles are removed with greater efficiency. Various classes of BSC are designed to meet requirements for biosafety levels 2, 3 and 4. To ensure that the equipment works properly the BSC needs to be maintenance, calibrated and re-certified regularly. These processes are usually done by private companies that sell the equipment. However, when Thailand started the BSC engineering control project in 2013, in collaboration with US CDC, the results showed that only 30 % of the BSC could pass the certification by NSF standard. Various problems were identified such as wrong installation, improper certification procedure, users lacked of understanding, etc. To tackle with these kinds of problems the BSC users should have knowledge on Biosafety engineering controls to be able to select, use and maintain the BSC properly. Furthermore, the user should be able to monitor the performance of the sub-contracts who sell the BSCs, perform certification and maintenance. At a national level, the ASEAN member states should have capacity to train laboratory staff on proper selection and use of BSC, to train bioengineers in- country to certify BSC.

In addition, increasing need for biosafety level 3 for handle of high risk pathogen and need for BSL-4 laboratory in ASEAN are seen. For Thailand, there are many BSL-3 laboratories throughout the country but the knowledge on commissioning and certification of BSL-3 labs are lacking. This leads to lack of capacity for governmental organization to control and regulate commissioning and inspection of these BSL-3 labs. Also, there is plan for Thailand MOPH to commission BSL-4 labs, therefore there is need to build capacity of MOPH staffs on good knowledge and comprehensive understanding on BSL-3 and BSL-4 design, structure, requirement and inspection.

(b) Regionality

(Show that the problem or issue affects more than one ASEAN Member States and requires regional action. This needed for the project to be considered an ASEAN Health Cooperation Project)

In the JEE, Lao PDR and Vietnam's results showed that the biosafety and biosecurity of these two countries shall be further improved. For Thailand, even though the biosafety and biosecurity policy are in place but inter-organization cooperation at emergency outbreak shall be further improved.

Therefore, the Regional Medical Sciences Center (RMSC) 8 Udothani which locates in upper north eastern part of Thailand and only 70 kilometers from Vientiane, Lao PDR, also easily access from Vietnam and Cambodia via the Udonthani airport and other travel means, has good location to serve as a regional training center for biosafety, biosecurity and biorisk management. RMSC 8 has a mission to serve as a training center for health laboratories in upper north eastern part of Thailand and they already have established the training labs that can accommodate such training. Therefore under this project the bilateral collaboration between Thailand RMSC 8 and Lao PDR Department of disease control in training the health laboratory staffs of Lao PDR for biosafety, BSC technology, biosecurity and biorisk management could be a pilot project and if it shows success, it can expand to cover for Vietnam or Cambodia.

(c) Project History

(If available, list related projects/activities previously or currently implemented relevant to the ASEAN Health Sector at the regional or global levels. Describe how these activities/projects complements them)

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Therefore, in this project, we aim to expand from the primary focus of BSC technology and certification toward harmonizing the Biosafety, Biosecurity and Bioengineering of the ASEAN through series of activities as elaborated below.

(d) The Beneficiaries

(Please state who will directly benefit from the stakeholders that will be engaged in this project activity. The proponent could also identify who could benefit indirectly)

Immediate beneficiaries: Department of Medical Sciences (DMSC), Ministry of Public Health (MOPH), Thailand, Thailand MOPH-US CDC collaboration and AFRIMS, Regional Medical Sciences Centre No. 8 (Udonthani) and Department of Disease Control, Ministry of Health, Lao PDR

Indirect beneficiaries are staffs of health laboratories of other AMS who will be nominated from their responsible organization in their countries for capacities building under the workshops and activities in this project.

VIII. PROJECT RESULT

Objectives	Results/ Outputs	Indicators	Means of Verification	Main Activities	Indictors	Means of Verification
Objective/outcome: (The intended physical activity, financial, institutional, social, environmental or other development results to which a project is expected to contribute)	(What results will the project lead to, for example any products and services or changes that are relevant to the achievement of objective(s))	(How will the project's activity achievement be measured? Please indicate feasible quantitative and qualitative measures)	(How will information be collected to support these indicators)	(List the actions or activities that your project will carry out to achieve the above results/outputs)		
1. Improvement and maintaining BSC standard and enhancing Bioengineering.	a. Acquire at least 2 sets of BSC certification equipment for loan to the competent participants for practicing under supervision from licensed instructor b. Provide workshop to support the previous	1. Identified participants of AMS shows improved capacity in class II BSC certification 2. Identified staff of Thailand MOPH and from selected AMS attended BSL-3 commissioning and BSL-4 regulations	- Evaluation of Workshop -NSF basic Class II BSC field certification exam. - Report and recommendation for BSL-3 commissioning and BSL-4 regulations -NSF enhanced Class II BSC field certification exam	1-1: Providing key persons with deep understanding on BSC technology and certification to improve and maintain BSC standard within the region 1-2: Enhance the bioengineering concepts on BSL-3 commissioning and	1. Number of participants who pass NSF basic Class II BSC field certification exam 2. number of materials / reports sent to AMS 3. Number of participants who pass NSF	1. List of participants who pass NSF basic Class II BSC field certification exam and their contacts 2. List of NSF enhanced Class II BSC field certification exam and their contacts 3. List of participants who

Objectives	Results/ Outputs	Indicators	Means of Verification	Main Activities	Indictors	Means of Verification
	<p>participants to achieve the NSF 49 accreditation on basic Class II BSC</p> <p>c. Support as many participants from AMS as possible to achieve NSF 49 accreditation on basic Class II BSC certification</p>	<p>3. At least 2 candidates from Thailand pass NSF enhanced Class II BSC field certification exam and get licensed</p> <p>4. Connects all participants between each other and to BSC users in need for assistance on BSC issues using a web portal that is to be developed in this project.</p>	-	<p>BSL-4 regulations in Thailand and ASEAN</p> <p>1-3 :To provide Thailand with at least 2 NSF 49 enhanced Class II BSC certifiers</p> <p>1-4 : Establish the web portal for Biosafety online-training and communication purposes</p>	<p><i>enhanced Class II BSC field certification exam</i></p> <p>4. A web-portal for Biosafety online-training and communication purposes</p>	<p>was trained and their contacts</p> <p>4. Documents and resources for Biosafety, Biosecurity and Biorisk Management that are available on the web portal</p> <p>5. Progress report and wrap-up report</p>
2. Biorisk Management Toolkit Harmonization	<p>a. A harmonized Biorisk management (BRM) toolkit for BRM trainer to use in their training that includes scenarios for training that is suitable for ASEAN region</p> <p>b. Provide</p>	<p>1. Identified participants from AMS are trained as BRM trainer using the ASEAN BRM toolkit</p> <p>2. BRM trainers delivers training to local health staffs in their countries using the developed</p>	<p>- <i>Evaluation of Workshop</i></p> <p>- <i>Evaluation of the trained participants who passed the ASEAN BRM workshop</i></p> <p>-<i>Evaluation of the ASEAN BRM toolkit that the participants (BRM trainers) used in their training that is</i></p>	<p>2-1: Biorisk Management Toolkit Harmonization</p> <p>2-2 Making of One Health Biorisk Management Toolkit</p>	<p>1. Number of <i>participants who passed the ASEAN BRM workshop</i></p> <p>2. <i>Evaluation scores of the ASEAN BRM harmonizing workshop</i></p> <p>3. <i>Number of times that the developed</i></p>	<p>1. List of participants who pass the <i>ASEAN BRM workshop</i></p> <p>2. <i>Evaluation scores of the ASEAN BRM harmonizing workshop more than 80%</i></p> <p>3. <i>Lists of workshop that used the developed ASEAN BRM toolkit is</i></p>

Objectives	Results/ Outputs	Indicators	Means of Verification	Main Activities	Indictors	Means of Verification
	workshop to support the previous BRM trainers to use the harmonized toolkit and provide refresh training c. Build a training program that combine both fundamental concepts on biosafety, biosecurity in the scenarios of animal and human health	ASEAN BRM toolkit 3. One Health Toolkit that capture the necessary concepts to mitigate the health crisis with interchange between animals and humans	<i>delivered to their staffs</i> <i>-The one health toolkit that is developed</i>		<i>ASEAN BRM toolkit is used for training purposes</i> 4. <i>The one health toolkit is developed</i>	<i>used</i> 4. <i>The one health toolkit is used to train the animal health and human health staff together</i> 5. Progress report and wrap-up report
3. Establish a Thailand regional training centre for Biosafety, Biosecurity and Biorisk Management in Bilateral Collaboration between Regional Medical Sciences Center (RMSC) 8	a. Acquisition of necessary equipment for Biosafety, Biosecurity and Biorisk management regional training center. b. Workshops for Biosafety cabinet technology,	1. RMSC Udonthani envisions of being a training center for medical sciences and health related laboratory sciences of the upper northeastern part of Thailand. This is to facilitate their	- <i>The training center is ready and is used for biosafety and biosecurity training</i> - <i>Evaluation of Workshop</i> - <i>Evaluation of the trained participants who passed the ASEAN BRM workshop</i>	1. Equipped the training laboratory of RMSC 8 with necessary equipment for Biosafety, Biosecurity and Biorisk management training 2. Provide 2 workshops on	1. Number of participants 2. <i>Evaluation scores of the workshops</i>	1. List of participants who attend workshops 2. Progress report and wrap-up report

Objectives	Results/ Outputs	Indicators	Means of Verification	Main Activities	Indictors	Means of Verification
Udonthani and Department of Disease Control of Lao PDR	<p>maintenance and certification and Biorisk management for hospital staffs from Lao PDR</p> <p>c. Biosafety and Biosecurity workshops for hospital laboratory staffs in health sector 8 (Upper northeastern) of Thailand</p> <p>d. Capacity building for staffs of regional medical sciences center Udonthani</p>	<p>training laboratory with equipment necessary for biosafety, biosecurity and biorisk management training</p> <p>2. Identified participants from Lao PDR are trained on biosafety, biosecurity, biorisk management and BSC technology</p> <p>3. Staffs from health laboratories in upper northeastern Thailand are trained for biosafety, biosecurity and biorisk management</p> <p>4. RMSC Udonthani has more staffs</p>		<p>Biosafety, BSC technology and Biorisk management for identified participants from Lao PDR (This activities is co-funded by Lao PDR proposed project under this round of Canada GPP)</p> <p>3. Provided 3 trainings (45 participants each) for staffs from health laboratories in upper north-eastern Thailand</p>		

Objectives	Results/ Outputs	Indicators	Means of Verification	Main Activities	Indictors	Means of Verification
		who are capable as Biosafety, Biosecurity and Biorisk Management trainers				

IX. PROJECT MANAGEMENT ARRANGEMENT (A and B should be completed if source of fund is from ASEAN Trust Fund)

(a) Management Arrangements

(Describe briefly the management structure of the clearly identify the responsible implementing agency to receive fund (if applicable), achievement of project results and submission of the completion report)

- The project management will be under the Department of Medical Sciences, Ministry of Public Health Thailand. Except for the activities proposed by Department of Disease Control, Ministry of Health, Lao PDR which is considered as a collaborative side project will be managed by Lao PDR DDC.
- The training will be organized in Thailand or any ASEAN countries as appropriate. Training facilities for practical exercise will be done at DMSc.

(b) Human Resource Inputs

(Specific type and number of personnel who are involved in the project activity)

Estimate number of staff : 3 Project consultants, 2 Technical Team Leaders , 3 Project coordinators, 15 scientists and 5 administrative staffs will devote to this project. All of them are full time government officials.

(c) Engagement with potential partner

(Identify potential partners that would be involve in the implementation of project activities)

Thailand MOPH-US-CDC collaboration project

Arm Force Research Institute for Medical Sciences (AFRIMS)

National Institute of Animal Health, Department of Livestock, Ministry of Agriculture and cooperatives, Thailand

FAO

(d) Monitoring and Evaluation Arrangements

- *Reports of progress and activities will be submitted to ASEAN Health cluster II and Canada GPP every 6 months*
- *Reports of progress and activities will be report to ASEAN Biosafety network meeting annually*
- *Projects will be assessed and visited annually or more frequently by the ASEAN member or Canada GPP*

X. PROJECT SUSTAINABILITY-300 WORDS MAX

(State how the output(s) of the project activities can be aligned or how this complement output of other ASEAN Health Clusters and/or non-health sector)

- Biosafety, Biosecurity and Biorisk Management are an essential component in public health laboratories working with infectious specimens. The content of the project will support and build capacity for safety in health laboratories in ASEAN as a required component for in the IHR, JEE and CBRN.
- The project will apply train-the-trainer approach to ensure that the participant countries will be able to establish their own training programs.
- Candidate participant will have to go through the process of selection from within their country

and also from the course committee and will be required to show their track record and their commitment on transferring the knowledge on Biosafety, Biosecurity and Biorisk management and building awareness of BSC proper use and certification in their country.

XI. GENDER AND OTHER CROSS CUTTING ISSUES

(If applicable, please identify gender and other cross cutting (i.e. economic, environment, labour, disaster, human right, etc) issues that the project can address)

There is no other gender and cross cutting issue.

XII. POTENTIAL RISK

(State the significant potential risks or threats within the proponent's control that would affect the success of the project, such as lack of capable human resources, security and political, etc.)

Risk/threat	Mitigation Strategy
Unable to invite the suitable person as the participants	Identify the suitable person through the existing network and key organization of AMS
Unable to carry out the proposed activities in the time limit	Lay out all activities using Gantt's chart and carefully monitor every activities progress Schedule activities to be in line with other possible major events to minimize the absent of the identified participants in order to attend other important events
Unable to use the budget efficiently or activities to be held efficiently because lack of political support	Make official agreement with management level staff and notification to the Deputy director of DMSC and possibly the Minister of Public Health