

NOTIFICATION OF THE DEPARTMENT OF MEDICAL SCIENCES
RE: CERTIFYING AN AGENCY OR A BODY WITH THE BIOSAFETY AND BIOSECURITY TRAINING COURSE

By virtue of the provisions in Chapter 1 Clause 6 and Chapter 2 Clause 9 of the Notification of the Department of Medical Sciences Re: Operator and Operation Personnel in accordance with the Pathogens and Animal Toxins Act B.E. 2558 (2015) B.E. 2561 (2018) prescribing that the operator and the operation personnel must be trained in biosafety and biosecurity pursuant to the course of an agency or a body declared by the Department of Medical Sciences for certifying, therefore, the Notification has been issued as follows.

Clause 1 In this Notification,

“Course” means the biosafety and biosecurity training course.

“Agency or Body” means an agency or a body of the government or a juristic person with the course(s).

“Certificate” means a certificate of an agency or a body with the course(s).

Clause 2 In applying for declaring to certify an agency or a body with the course(s), the said agency or body shall submit an application in writing to the Department of Medical Sciences together with the following documents.

- (1) A certificate of Juristic Person Registration or a document stating the juristic person status of an agency or body
- (2) Course
- (3) Name list of and qualifications of the lecturers

Clause 3 The course(s) pursuant to Clause 2 (2) shall at least contain the following details.

- (1) Name of the Course
- (2) Rational Criterion
- (3) Objective of the Course
- (4) Target Group
- (5) Operating Period
- (6) Operating Procedure
- (7) Operating Place
- (8) Assessment Procedure
- (9) Person in charge of the operation
- (10) Course Content

Clause 4 An agency or a body shall arrange a lecturer with any of the following qualifications.

- (1) Graduate not below the level of Bachelor’s degree in microbiology area or in the area relating to pathogens or animal toxins in the academic degree level in total of not less than twelve credits; and have knowledge or experiences relating to the training topics;
- (2) Graduate not below the level of Bachelor’s degree in other programs and having at least three years of continuous work experience in pathogens or animal toxins; or pass the biosafety and biosecurity training course being equivalent to the course in the attachments to this notification.

(Unofficial Translation)

Clause 5 An agency or a body shall arrange the training assessment by defining the pass criteria of assessment for not less than seventy percent.

In passing an assessment pursuant to paragraph one, an agency or a body shall issue a document stating the pass of assessment. Such document shall be valid not more than three years.

Clause 6 Upon receipt of the application and document pursuant to Clause 2, the Department of Medical Sciences shall verify the application and the application documentation and issue a certificate to an agency or a body upon finding that the application and the application documentation contain the valid statements and the course consists of the equivalent details or not less than the course in the attachments to this notification.

In the case where the application or the application documentation is invalid, the Department of Medical Sciences shall give a written notice to the agency or the body. It may request to send an additional information within the specified period.

Upon operation pursuant to paragraph one, the Department of Medical Sciences shall prepare and disseminate a list of the certified agencies or bodies accordingly.

Clause 7 In the case where the application or the application documentation is invalid, and an agency or a body fails to take a corrective action within the specified period pursuant to Clause 6, the Department of Medical Sciences shall repeal the application and notify the reason to the agency or the body within thirty days from the notification date of the invalidity.

Clause 8 The certificate pursuant to Clause 6 shall be valid for five years from the issuance date of a certificate, and the certificate shall be in line with the form in the attachments to this notification.

Clause 9 In the case where an agency or a body that is granted for a certificate intends to alter the details of the course(s), it shall notify the Department of Medical Sciences for approval prior to operation.

Clause 10 An agency or a body that intends to apply for renewal of a certificate shall submit an application in writing to the Department of Medical Sciences prior to the date of expiry not less than sixty days.

The provisions in Clause 6, Clause 7, and Clause 8 shall be used in considering the renewal of a certificate *mutatis mutandis*.

Each renewal of a certificate can be performed for five years per term from the date of expiry of the primary certificate.

Clause 11 In the case where a certificate is lost, destroyed, or damaged in materiality, an agency or a body shall submit an application for a replacement certificate to the Department of Medical Sciences. After approval, a replacement certificate shall be issued to an agency or a body.

In issuing a replacement certificate, the primary certificate form shall be used and affixed with the statement of "Replacement" with red letter on the top of the said certificate.

Notified on the 24th day of October B.E. 2561 (2018)

Opas Karnkawinpong

Director-General of the Department of Medical Sciences

This translation is provided by Department of Medical Sciences as the competent authority for information purposes only. Whilst Department of Medical Sciences has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

Biosafety and Biosecurity Training Course

(in the Annex of the Notification of the Department of Medical Sciences
Re: Certifying an Agency or a Body with the Biosafety and Biosecurity Training Course)

Theory

No.	Topics	Objective	Course Content	Period*
1	Laws and rules relating to biosafety and biosecurity	To provide knowledge in the matter of the requirements and practical procedures pursuant to the requirements of laws and rules relating to biosafety and biosecurity of Thailand and internationally prescribed	Pathogens and animal toxins law, occupational health law, United Nations requirements, World Health Organization requirements	1 hour
2	Principle of biosafety and biosecurity	To provide knowledge relating to the principle, element, and practice for biosafety and biosecurity	1. Meaning, element, and principle of biosafety 1.1 Laboratory hazard 1.2 Classification of pathogens and animal toxins based on a risk level 1.3 Biosecurity level (BSL) of a laboratory 1.4 Good Microbiological Practice 2. Meaning, element, and principle of biosecurity 2.1 Structure and premise safety 2.2 Personnel security 2.3 Biological agent security	1 hour 30 minutes

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No.	Topics	Objective	Course Content	Period*
			2.4 Biological agent transportation or movement security 2.5 Information security	
3	Biorisk management	To provide knowledge in the matter of the significance, and the principle of biorisk management	1. Significance of biorisk management 2. Risk assessment 3. Biorisk management and control	1 hour
4	Biosafety practice	To provide knowledge relating to biosafety practice	1. Tool and equipment emplacement facility design 2. Good Microbiological Practice 3. Safety equipment	45 minutes
5	Personal Protective Equipment (PPE)	To provide knowledge relating to each type of PPE, type selection in usability, usability, and post-usability management	1. Type of PPE 2. Selection of PPE type 3. PPE usability 4. Post-usability PPE management	1 hour
6	Safety equipment	To provide knowledge relating to the principle, type, usability selection, usability, and maintenance of safety equipment	1. Biological safety cabinet (BSC), Laminar flow, and Fume hood 1.1 Equipment differences 1.2 Kind and type 1.3 Working principle 1.4 Appropriate usability 1.5 Maintenance 1.6 Certification audit	1 hour

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No.	Topics	Objective	Course Content	Period*
			2. Centrifuge 2.1 Appropriate usability 2.2 Maintenance	
7	Pathogen destruction	To provide knowledge relating to the principle and procedure of pathogen destruction	1. Type, principle, and procedure of pathogen destruction 2. Selection of a suitable procedure 3. Destruction efficiency assessment	1 hour
8	Pathogen transportation	To provide knowledge relating to the procedure of packaging and transportation of pathogens and animal toxins	Practical procedure in packaging and transportation of pathogens and animal toxins	1 hour
9	Infectious waste management	To have knowledge and understanding relating to infectious waste management	1. Public health law 2. Collection, movement, and disposal of different types of wastes, such as general waste, infectious waste, sharp waste, radiation waste, chemical waste, toxic waste, and carcass	1 hour
10	Biological agent spill management	To provide knowledge and understanding relating to the management in the event of biological agent spill	1. Element of biological spill kit 2. Practical procedure upon the event of biological agent spill in operations place, in biological safety cabinet, and in centrifuge 3. Accident reporting	1 hour
11	Assessment	To measure training	Theoretical examination	

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Practice

No.	Topics	Objective	Course Content	Period*
1	Training exercise in the tool and equipment emplacement facility design in Operations Place	To understand the principle of the tool and equipment emplacement facility design in Operations Place	Training exercise in planning in Operations Place, separation of clean area and contaminated area, consideration of air flow direction, and emplacement of tools and equipment affecting biosafety, determination of entrance route of humans, samples, and infectious materials, and area management for biosecurity	45 minutes
2	Training exercise in wearing and removing Personal Protective Equipment (PPE)	To perform training exercise in wearing and removal of PPE	1. Training exercise in PPE wearing and removal 2. Training exercise in post-usability PPE management 3. Exercise in hand washing	1 hour
3	Training exercise in biological agent spill management	To ensure the proper practice in the event of biological agent spill	1. Simulation in the event of biological agent spill in Operations Place, in biological safety cabinet, and in centrifuge 2. Training exercise in use of biological spill kit 3. Exercise in writing the incident report	1 hour
4	Assessment	To measure training	Practical examination **	

Condition * The training period in each topic may be changed based on the suitability of the course. However, total period throughout the course must not be less than 14 hours.

** The suitability of the course shall be considered in a practical examination.

(Unofficial Translation)

No.

Certificate

This Certificate is given to certify that,
located at No.
....., is an agency/a body with the biosafety and
biosecurity training course(s) pursuant to the provisions in Chapter 1 Clause 6, and Chapter 2 Clause 9 of the
Notification of the Ministry of Public Health Re: Operator and Operation Personnel in accordance with the
Pathogens and Animal Toxins Act B.E. 2558 (2015) B.E. 2561 (2018), whereas
.....must strictly carry out in accordance with the course(s) as in the attachments.

From the date of
Date of expiry of the Certificate

Director-General of the Department of Medical Sciences

