

NOTIFICATION OF THE DEPARTMENT OF MEDICAL SCIENCES
RE: CERTIFYING AN AGENCY OR A BODY WITH THE COURSE OF TRAINING IN OPERATIONS PLACE LEVEL 3

By virtue of the provisions in Chapter 2 Clause 10 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 operation personnel of the Operations Place Level 3 must pass the training 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 training course in Operations Place Level 3.

“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 have the working experiences in Operations Place Level 3 not less than three years or pass the training course in Operations Place Level 3 being equivalent to the course as 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 eighty 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 as 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 as 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

Course of Training in Operations Place Level 3

(in the Annex of the Notification of the Department of Medical Sciences

Re: Certifying an Agency or a Body with the Course of Training in Operations Place Level 3)

Theory

No.	Topics	Objective	Course Content	Period*
1	Principle of Biosafety and Biosecurity	To review knowledge and understanding on the principle of biosafety and biosecurity.	<ol style="list-style-type: none">1. Principle of Biosafety and Biosecurity2. Classification of pathogens and animal toxins based on the risk level3. Biosafety level (BSL) of a laboratory4. Exposure to pathogens and means of infection which may be arisen in Operations Place Level 35. Pathogen destruction	1 hour
2	Tool and equipment emplacement facility design in Operations Place Level 3	To provide knowledge relating to the principle of the tool and equipment emplacement facility design in Operations Place Level 3	<ol style="list-style-type: none">1. Principle of the tool and equipment emplacement facility design in Operations Place Level 32. Safety equipment3. Laboratory area management4. Area management for biosecurity5. Inspection on the preparation and safety of laboratory, tools, and equipment	2 hours
3	Inspection and maintenance of Operations Place Level 3	To provide knowledge and awareness on the significance of inspection and maintenance of working system of Operations Place Level 3	<ol style="list-style-type: none">1. Destruction of pathogens in Operations Place Level 32. Inspection of physical system and inspection of tools and equipment in laboratory3. Inspection of HEPA filter spill4. Inspection of pressure and air flow direction	1 hour

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No.	Topics	Objective	Course Content	Period*
			5. Inspection of wall condition 6. Inspection of safety and security alert system	
4	Work Standards in Operations Place Level 3	To provide knowledge relating to work standards in Operations Place Level 3	Work Standards in Operations Place Level 3 1. Use of safety equipment, such as Biological safety cabinet (BSC), centrifuge, pipette, etc. 2. Necessary regulations 2.1 Personnel management 2.2 Tool and equipment management 2.3 Sample management 2.4 Infectious waste management 2.5 Determination of entrance route of human, sample, article, and waste 2.6 Determination of a measure for safety while working, such as use of Buddy system, monitoring using CCTV	2 hours
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	Response in the event of emergency	To provide knowledge relating to the process and problem-solving upon the event of emergency while working in Operations Place Level 3	1. Practical procedure upon the event of biological agent spill in a laboratory, in Biological safety cabinet (BSC), and in centrifuge.	1 hour

Course of Training in Operations Place Level 3

(in the Annex of the Notification of the Department of Medical Sciences

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No.	Topics	Objective	Course Content	Period*
			2. Evacuation or relocation in the following cases. 2.1 In the event of biological agent spill occurrence 2.2 In the event of accident from the cut of a sharp thing 2.3 Unconsciousness of a colleague 2.4 Failure of HVAC (Heating, Ventilation & Air-Conditioning) System 2.5 In the event of fire	
7	Assessment	To measure training	Theoretical examination	

Course of Training in Operations Place Level 3

(in the Annex of the Notification of the Department of Medical Sciences

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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 Level 3	To understand the principle of the tool and equipment emplacement facility design in Operations Place Level 3	Training exercise in planning in Operations Place Level 3, 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 human, sample, article, and waste, and area management for biosecurity	2 hours
2	Training exercise in wearing and removing Personal Protective Equipment (PPE)	To be properly and safely wearable and removable in Operations Place Level 3	1. Demonstration of Fit testing of safety mask wearing 2. Demonstration of Power air Purifying Respirator (PAPR) Availability Inspection Method 3. Training exercise in PPE wearing 4. Training exercise in PPE removal	1 hours
3	Training exercise in entry-exit into and from Operations place Level 3	To ensure the proper and safe entrance of Operations Place Level 3	1. Preparation and inspection of safety prior to entry into a laboratory 2. PPE wearing 3. PPE removal 4. Safety inspection prior to exit from a laboratory	2 hours
4	Training exercise in emergency response	To know the practice in the event of emergency in Operations Place Level 3	Simulation of an emergency and practical exercise 2.1 Practice in the event of biological agent spill in laboratory, in biological safety cabinet, and in centrifuge	3 hours

(Unofficial Translation)

Course of Training in Operations Place Level 3

(in the Annex of the Notification of the Department of Medical Sciences

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No.	Topics	Objective	Course Content	Period*
			2.2 Practice in the event of accident from the cut of a sharp thing 2.3 Practice in the event where a colleague is unconscious. 2.4 Practice in the event of failure of HVAC (Heating, Ventilation & Air-Conditioning) System 2.5 Practice in the event of fire	
5	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 16 hours.

(Unofficial Translation)

No.

Certificate

This Certificate is given to certify that,
located at No.
....., is an agency/a body with the course(s) of
training in Operations Place Level 3 pursuant to the provisions in Chapter 2 Clause 10 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

