(Unofficial Translation)

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: OPERATORS AND OPERATION PERSONNEL UNDER PATHOGENS AND ANIMAL TOXINS ACT, B.E. 2558 (2015) B.E. 2561 (2018)

Whereas it is expedient to specify qualifications, number and duties of the operator and operation personnel who operates the production, import, export, sale, transit or possession of pathogens or animal toxins in order to be clear and appropriate.

By the virtue of the provisions of Section 5 paragraph one and Section 6 (5) of the Pathogens and Animal Toxins Act, B.E. 2558 (2015), the Minister of Public Health with the advice of Pathogens and Animal Toxins Committee hereby issues the notification as follows:

Clause 1 This notification is called “The Notification of the Ministry of Public Health entitled Operators and Operation Personnel under Pathogens and Animal Toxins Act, B.E. 2558 (2015), B.E. 2561 (2018)”

Clause 2 This notification shall come into force as from the day following date of its publication in the Government Gazette.

Clause 3 In this notification:

"Operational facility" means operation facility according to the notification of the Ministry of Public Health on the characteristics of the place of production or possession of pathogens and animal toxins as well as the operations related to pathogens and animal toxins, B.E. 2561 (2018).

"Operation” means the production, import, export, sale, transit or possession of pathogens or animal toxins determining tools, equipment, accompanying documents, labels, containers or packages for each container of pathogens and animal toxins, and quantities or the number of pathogens and animal toxins, as well as security systems and quality systems of production, import, export, sale, transit or possession of pathogens and animal toxins.

Clause 4 This notification shall not apply to persons who operate the production, import, export, sale, transit or possession of Group 1 Pathogens.

Clause 5 Have the Director-General of Department of Medical Sciences act in charge in accordance with this announcement.

CHAPTER I
QUALIFICATIONS AND DUTIES OF THE OPERATOR

Clause 6 Qualifications of an operator of level 2 or level 3 operational facility

(1) Having completed at least a bachelor's degree in Medicine, Veterinary Science, Dentistry, Nursing Science, Pharmaceutical Science, Medical Technology, Veterinary Technology, Science Program in Microbiology or having studied in Microbiology or related to pathogens or animal toxins in undergraduate degree with a total of not less than twelve credits or having graduated with a degree in other fields and having at least three years of continuous work experience in pathogens or animal toxins;

In the case of operations involving animal toxins or biological substance with non-proteinaceous infectious particle and without concerning pathogens, the operator must have the qualifications under paragraph one or have completed at least a bachelor's degree in Toxicology or have studied in Toxicology or related to Toxicology at a total degree of not less than three credits.

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.

The qualifications under paragraph one and paragraph two shall not apply to operators with at least five years of continuous experience in pathogens or animal toxins operations up to the effective date of this notification.

(2) Being at least 20 years of age;

(3) Not being the unsound mind person;

(4) Not being incompetent or quasi-incompetent;

(5) Being a permanent worker in an agency or organization to which the operating facility belongs, and not being an operator in other operational facility;

(6) Being a person whose name appears on a certificate of notification or a license as the operator.

Have the operator receives biosafety and biosecurity training courses certified by the agencies or organizations under the Department of Medical Sciences within one hundred and eighty days from the date of receiving the certificate of notification or the date of receiving the license and to be retrained at least once every three years.

Clause 7 The qualifications of operators operate with Group 4 Pathogens or Group 3 Animal Toxins shall be in accordance with the criteria established by the World Health Organization and approved by the Pathogens and Animal Toxins Committee.

Clause 8 The operator has the following duties:

(1) Control operations involving pathogens or animal toxins in accordance with the Pathogens and Animal Toxins laws;

(2) Control the performance of operation personnel, persons working in the operational facility or other authorized persons entering the operational facility and prevent other unrelated individuals from entering the operational facility;

(3) Stipulate procedures and work instructions relating to pathogens or animal toxins;

(4) Prepare a pathogen or animal toxin monthly account as specified in the certificate of notification or the license;

(5) Control the safety system and the quality system of operations as follows:

(a) Maintain the security of the place of production or possession of pathogens and animal toxins;

(b) Prevent the access to the place of production or possession of pathogens or animal toxins from unrelated persons;

(c) Maintain the security of information about pathogens or animal toxins;

(d) Provide and control the use of personal protective equipment as appropriate and in line with groups of pathogens or animal toxins;

(e) Determine procedures for collection, storage, and transport and the destruction of infectious waste in accordance with the law on public health;

(f) Provide investigation reports and record of accidents caused by operations involving pathogens or animal toxins;

(g) Provide health surveillance and immunization for the operation personnel and others concerned persons;

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CHAPTER II
QUALIFICATIONS AND DUTIES OF THE OPERATION PERSONNEL

Clause 9 Qualifications of operation personnel of level 2 operational facility

(1) Having completed at least a bachelor's degree in Medicine, Veterinary Science, Dentistry, Nursing Science, Pharmaceutical Science, Medical Technology, Veterinary Technology, Science Program in Microbiology or having studied in Microbiology or related to pathogens or animal toxins in undergraduate degree with a total of not less than six credits or having graduated with a degree in other fields and having at least three years of continuous work experience in pathogens or animal toxins;

In the case of operations involving animal toxins or biological substance with non-proteinaceous infectious particle and without concerning pathogens, the operation personnel must have the qualifications under paragraph one or have completed at least a bachelor's degree in Toxicology or have studied in Toxicology or related to Toxicology at a total degree of not less than three credits.

The qualifications under paragraph one and paragraph two shall not apply to operation personnel with at least five years of continuous experience in pathogens or animal toxins operations up to the effective date of this notification.

(2) Being at least 20 years of age;

(3) Not being the unsound mind person;

(4) Not being incompetent or quasi-incompetent;

(5) Being a person whose name appears on a certificate of notification or a license as the operation personnel.

Have the operation personnel receive biosafety and biosecurity training courses certified by the agencies or organizations under the Department of Medical Sciences within one hundred and eighty days from the date of receiving the certificate of notification or the date of receiving the license and to be retrained at least once every three years.

Clause 10 Operation personnel of level 3 operational facility must meet the qualifications in Clause 9 and have additional qualifications including passing training courses certified by agencies or organizations under the Department of Medical Sciences or have at least six months of operating experience at level 3 operational facility.

Clause 11 The qualifications of operation personnel operate with Group 4 Pathogens or Group 3 Animal Toxins shall be in accordance with the criteria established by the World Health Organization and approved by the Pathogens and Animal Toxins Committee.

Clause 12 The operation personnel shall have the following duties:

(1) Carry out procedures and work instructions in accordance with the law on pathogens and animal toxins;

(2) Prepare a pathogen or animal toxin monthly account as specified in the certificate of notification or the license;

(3) Implement the following safety and quality systems:

(a) Follow the safety measures of the place of production or possession of pathogens and animal toxins;

(b) Systematically store information with protection against damage and loss as well as secure the data about pathogens or animal toxins;

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(c) Use the personal protective equipment appropriately and conform with groups of pathogens or animal toxins;

(d) Operate, maintain and inspect the quality of safety equipment in the operational facility;

(e) Collect, storage, transport and destroy infectious waste in accordance with the law on public health;

(f) Report an accident arising from the operations related to pathogens and animal toxins to the operator.

(4) Control the performance of personnel working in the operational facility or other authorized persons entering the operational facility;

CHAPTER III
NUMBER OF THE OPERATOR AND OPERATION PERSONNEL

Clause 13 The applicant for a certificate of notification or a license must engage at least one operator and operation personnel in each operational facility. An operator and an operation personnel may be the same person.

The Director-General may designate the number of operators or operation personnel in excess of the prescribed number under paragraph one, taking into account the nature of the operation, number of items or quantity including hazard level of pathogens or animal toxins.

Clause 14 In the event that the operator or the operation personnel releases from duties which causes the incomplete number of operator and operation personnel as specified, have the person receiving the certificate of notification or the licensee carry out the following procedures:

(1) Immediately notify the Director-General of the release of duties of the operator or the operation personnel as the case may be;

(2) Engage an operator and an operation personnel to act on behalf of them within ninety days from the date on which an operator and an operation personnel release the duties under paragraph one.

TRANSITORY PROVISIONS

Clause 15 The person controlling the production, import, export, sale, transit or possession of pathogens or animal toxins permitted under the Pathogen and Animal Toxicity Act B.E. 2525 (1982) is able to perform duties until the expiration of the license.

Notified on the 24th day of January B.E. 2561 (2018)
Piyasakol Sakolsatayadorn
The Minister of Public Health

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