(Unofficial Translation)

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: CHARACTERISTICS OF THE PLACE OF PRODUCTION OR POSSESSION OF AND OPERATIONS ON PATHOGENS AND ANIMAL TOXINS B.E. 2563 (2020)

By the virtue of Section 5 Paragraph one and Section 6 (4) of the Pathogens and Animal Toxins Act B.E. 2558 (2015), the Minister of Public Health hereby issues the notification following the advice of the Pathogens and Animal Toxins Committee as follows:

Clause 1 This notification is called "The Notification of the Ministry of Public Health Re: Characteristics of the Place of Production or Possession of and Operations on Pathogens and Animal Toxins B.E. 2563 (2020)."

Clause 2 This notification shall come into force after 90 days from the date of its publication in the Government Gazette.

Clause 3 The Notification of the Ministry of Public Health Re: Characteristics of the Place of Production or Possession of and Operations on Pathogens and Animal Toxins B.E. 2561 (2018) shall be repealed.

Clause 4 In this notification,

"Operate" means production, import, export, sale, transit, or possession of pathogens or animal toxins including tools, equipment, accompanying documents, labels, containers or packages, and amount or quantity of pathogens or animal toxins as well as safety systems and quality systems of production, import, export, sale, transit, or possession of pathogens or animal toxins.

"Operational site" means place of production or place of possession of pathogens or animal toxins.

"Place of production" means spaces, areas, buildings, rooms, or other places used for breeding, mixing, cooking, converting, adding, synthesis, packing or compiling pathogens or animal toxins as well as related possessions.

"Place of possession" means spaces, areas, buildings, rooms, or other places used for possessing pathogens or animal toxins without breeding, mixing, cooking, converting, adding, synthesis, packing or compiling pathogens or animal toxins.

"Biological safety cabinet" means cabinets designed for use with biological hazards which can protect operators and the environments from getting or being contaminated by pathogens or animal toxins with key elements including high efficiency particulate air filter (HEPA filter), internal ventilation control system, and the requirement of exhaust air to pass through the HEPA filter before exhausting.

"Fume hood" means hoods designed for use with substances containing vapors, odors or fumes to protect operators from exposure to hazardous vapors, odors or fumes.

Clause 5 The Director-General of the Department of Medical Science shall be in charge of enforcement of and have the power to decide the compliance with this notification.

CHAPTER I
General Provisions

Clause 6 Operational sites shall be divided into four levels based on operations on pathogens or animal toxins as follows:

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.

(1) Operation Site Level 1 consists of operational sites used to operate Group 1 Pathogens.

(2) Operation Site Level 2 consists of operational sites used to operate pathogens or animal toxins as follows:

(A) Group 1 Pathogens

(B) Group 2 Pathogens

(C) Group 3 Pathogens which can be operated at Operational Site Level 2 Enhanced (biosafety level 2 enhanced: BSL-2 enhanced) as specified in the notification issued under Section 6 (1)

(D) All groups of biological substances

(E) Group 3 Biological Substances which can be operated at Operation Site Level 2 Enhanced (biosafety level 2 enhanced: BSL-2 enhanced) as specified in the notification issued under Section 6 (1)

(F) All groups of animal toxins

(3) Operation Site Level 3 consists of operational sites used to operate pathogens or animal toxins as follows:

(A) Group 1 Pathogens

(B) Group 2 Pathogens

(C) Group 3 Pathogens which can be operated at Operational Site Level 2 Enhanced (biosafety level 2 enhanced: BSL-2 enhanced) as specified in the notification issued under Section 6 (1)

(D) Group 3 Pathogens

(E) All groups of biological substances

(F) Group 3 Biological Substances which can be operated at Operational Site Level 2 Enhanced (biosafety level 2 enhanced: BSL-2 enhanced) as specified in the notification issued under Section 6 (1)

(G) All groups of animal toxins

(4) Operation Site Level 4 consists of operational sites used to operate pathogens or animal toxins from all groups.

CHAPTER II
Operation Site Level 1

Clause 7 Operation Site Level 1 shall have the following characteristics:

(1) being a closed space or a sectioned room, whose inside is visible and which is sufficient for production or possession;

(2) having walls, floors, and ceilings designed and constructed using durable and easy-to-clean materials;

(3) having a door which is lockable;

(4) having equipment and tools sufficient for the quantity produced;

(5) having sturdy tables which can carry the weight of the quantity produced, have waterproof surface, can be easily cleaned, and are resistant to acids, alkalis, and disinfectants;

(6) having sturdy chairs made of non-absorbent and easy-to-clean materials with the appropriate size and sufficient quantity for operators;

(7) having hand-washing basins in areas of operations;

(8) having a space, an area, or a room for cleaning used equipment or materials;

(9) having a space, an area, or a room for collecting and storing solid waste by separating infectious waste from other types of solid waste with measures to prevent access by unrelated persons, animals and insects;

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.

(10) having sound and temperature at a level that does not affect work and health of operators; and

(11) having adequate lighting for operations.

The conditions in (4), (5), and (6) shall not apply to possession without production.

Clause 8 Operation Site Level 1 used with animals in operations on pathogens shall have the same characteristics as specified in Clause 7 and the following additional characteristics:

(1) being an animal room separate from other rooms equipped with appropriate ventilation and temperature control;

(2) having a room floor made of materials that are easy to clean, smooth, strong, able to carry the weight, waterproof, and acid and alkali resistant. In case of floor drain, there shall be a tightly closed lid that can only be opened when draining water;

(3) having a self-closing door; and

(4) having characteristics of places, equipment, and animal care management which are in accordance with the laws on animals for science.

Clause 9 Operational Site Level 1 shall have tools and equipment for operations on pathogens as follows:

(1) containers or packages of tightly closed containers which does not leak;

(2) tools and equipment suitable for storing containers;

(3) tools and equipment for transporting or moving which prevent containers from falling;

(4) waste bins with lids which can be opened without a hand touch;

(5) tools and equipment for destroying pathogens such as an autoclave or other appropriate methods for destroying pathogens;

(6) equipment or saline solution for eye wash;

(7) first aid kits; and

(8) biological spill kits with a minimum of liquid disinfectants, absorbent materials and personal protective equipment consisting of operating clothes, rubber gloves, safety glasses, and face masks as well as equipment for collecting contaminated materials such as tweezers, dustpan sets, and garbage bags for infectious waste.

Clause 10 Containers or packages of containers specified in Clause 9 shall be labelled with information about scientific names and dates of production or containment.

Clause 11 Operational Site Level 1 shall have at least the following safety and quality systems for operations on pathogens:

(1) having security of place of production or possession and controls of procedures on storage, production, import, export, sale, transit, or possession;

(2) having measures to control access by unrelated persons;

(3) using technically appropriate personal protective equipment;

(4) having collection, storage, moving, and disposal of infectious solid waste which are in accordance with the laws on public health;

(5) having technically appropriate cleaning of materials, equipment, and contaminated materials;

(6) recording transactions and quantities of productions or possessions;

(7) having roper accident reporting and investigations;

(8) having practices for prevention and control of animals and insects in the operational sites; and

(9) having measures to prevent the spread of contamination to the environment.

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.

CHAPTER III
Operational Site Level 2

Clause 12 Operational Site Level 2 shall have the same characteristics as specified in Clause 7 and the following additional characteristics:

(1) having measures to control people with the right to enter and exit; and

(2) having a "Biohazard" sign on the doors.

The "Biohazard" sign shall look similar to the attachment to this notification.

Clause 13 Operational Site Level 2 which uses animals in operations on pathogens shall have the same characteristics as specified in Clause 8 and Clause 12 and shall have a single air inflow direction, exhaust air duct, and other measures to prevent the spread of pathogens.

Clause 14 Operational Site Level 2 with operations related to carcasses, animal remains, parts, organs, tissues, or other specimens from carcasses or animal remains which may be contaminated with pathogens shall have the same characteristics as specified in Clause 13 and the following additional characteristics:

(1) In case of dissections of carcasses or animal remains, an area or a room shall specifically be provided for the dissections, except in the case of dissection of large animal remains which cannot be conducted in the specific area or room for animal remain dissection, appropriate measures to protect and prevent people from the spread of pathogens shall be in place;

(2) In case of operations related to parts, organs, tissues or other specimens from carcasses or animal remains which may be contaminated with pathogens, the operations shall be conducted in biological safety cabinet and a specific space for collecting or storing parts, organs, tissues or other specimens from carcasses or animal remains. In case that the requirements cannot be met, appropriate measures to protect and prevent people from the spread of pathogens shall be in place; and

(3) Having a space, an area, or a room for collecting carcasses, animal remains, parts, organs, tissues, or other specimens from carcasses or animal remains as well as contaminated solid waste waiting for destruction with destruction procedures that are able to prevent the spread of pathogens.

Clause 15 Operational Site Level 2 shall have the same tools and equipment for operating on pathogens or animal toxins as specified in Clause 9 and the biological safety cabinet as an addition.

In case of operational sites which operate on animal toxins without operations on pathogens, a biological safety cabinet or a fume hood shall be in place as appropriate.

In case of biological safety cabinet or fume hoods, the requirement does not apply to possessions without production.

Clause 16 Operational Site Level 2 which operates on biological substances shall have the same characteristics as specified in Clause 12 and measures to destruct the biological substances.

Clause 17 In case of production or possession of pathogens or animal toxins, the pathogens or animal toxins shall be contained at least in double-layered containers with the following characteristics:

(1) The inner layer of the containers shall be completely sealed, waterproof or liquid proof, and durable, not easy to break; and

(2) The outer layer of the containers shall be completely sealed, waterproof or liquid proof, durable, not easy to break, and able to contain liquid or others in case the inner layer of the containers breaks or leaks.

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.

Clause 18 Containers or packages of containers for pathogens or animal toxins shall be labelled as specified in Clause 10.

Clause 19 Information about pathogens or animal toxins possessed shall have the following details:

(1) In case of operations on Group 3 Pathogens which can be conducted in Operational Site Level 2 Enhanced as specified in notifications issued under Section 6 (1), pathogen safety data sheets (PSDS) shall be provided and include types, sources of pathogens, disease carriers, disease transmission, pathogenesis, symptoms, treatments and vaccines, personal protective equipment, first aid in case of accidents, destruction methods, and disposal methods; and

(2) In case of operations on animal toxins or biological substances, safety data sheets (SDS) of animal toxins or biological substances shall be provided and include types, sources, LD_{50}, hazard, treatments, personal protective equipment, first aid in case of accidents, destruction methods, and disposal methods.

Clause 20 The amounts or quantities of pathogens or animal toxins which can be produced or possessed shall take into account the readiness, biosafety, and biosecurity of operational sites.

Clause 21 Operational Site Level 2 shall have the same safety and quality systems as specified in Clause 11 and the following additional characteristics:

(1) having documents specifying procedures, methods, or work standards and having designs of safety and quality systems which are related to operations on pathogens or animal toxins;

(2) storing data in a systematic way to prevent damage and loss;

(3) having a list of people with access to information on pathogens or animal toxins and measures to prevent other unrelated persons from accessing the information;

(4) making a list of pathogens or animal toxins and keeping it updated with at least the following details:

(A) scientific names of pathogens or animal toxins;

(B) level of risk or hazard of pathogens or animal toxins as specified in notifications issued under Section 18 and Section 19;

(C) the number of containers indicating the volume or weight of pathogens or animal toxins;

(D) places for storing pathogens or animal toxins; and

(E) information on the deliveries of pathogens or animal toxins.

Clause 22 Operational Site Level 2 Enhanced (biosafety level 2 enhanced: BSL-2 enhanced) shall have the following additional details:

(1) Separating laboratories for operations; and

(2) Having technically appropriate personal protective equipment.

CHAPTER IV
Operational Site Level 3

Clause 23 Operational Site Level 3 shall have the same characteristics as specified in Clause 12 and the following additional characteristics:

(1) being a completely sealed room to allow for effective destruction of pathogens and prevention of the spread of the pathogens to the outside;

(2) having an anteroom or air-lock fitted with automatic-control doors;

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.

(3) having HEPA filters to filter exhaust air released from the laboratories;

(4) having negative-pressured temperature and humidity control systems and a single air inflow direction;

(5) having pathogen destruction systems using waste water with heat or chemicals (kill tank) before releasing waste water from laboratories; and

(6) having pathogen destruction equipment such as autoclave or other appropriate methods of destruction.

Clause 24 Operational Site Level 3 which use animals in operations on pathogens shall have the same characteristics as specified in Clause 13 and Clause 23 and the following additional characteristics:

(1) having a space or a room for operations on animals which is separated from other areas with entrances that are separate from the exits, completed sealed doors, and measures to prevent pathogen contamination after work;

(2) having sealed animal cabinets with air inlet filters (isolator) or animal rooms which can control the spread of pathogens as effectively as sealed animal cabinets;

(3) having an anteroom at the entrance;

(4) having a shower room or a clean station for decontamination, clothing change before entering and after exiting animal rooms;

(5) having inlet and exhaust air filtration using HEPA filters;

(6) having a system to prevent reverse airflow to other areas;

(7) having an autoclave installed in areas where animals are kept; and

(8) having equipment, methods, or measures to manage the disposal of animal remains and waste from animal rooms.

Clause 25 Operational Site Level 3 shall have the same tools and equipment for operations on pathogens and animal toxins as specified in Clause 9 and the following additional characteristics:

(1) biological Safety cabinets; and

(2) having technically appropriate personal protective equipment.

The requirement in (1) shall not apply to possession without production.

Clause 26 In case of production or possession of pathogens or animal toxins, the pathogens or animal toxins shall be contained at least in double-layered containers with the same characteristics as specified in Clause 17.

Clause 27 Containers or packages of containers of pathogens or animal toxins shall be labelled as specified in Clause 10.

Clause 28 Information about pathogens or animal toxins possessed shall have the following details:

(1) In case of operations on Group 3 Pathogens or Group 3 Pathogens which can be conducted in Operational Site Level 2 Enhanced as specified in notifications issued under Section 6 (1), pathogen safety data sheets (PSDS) shall be provided and include types, sources of pathogens, disease carriers, disease transmission, pathogenesis, symptoms, treatments and vaccines, personal protective equipment, first aid in case of accidents, destruction methods, and disposal methods; and

(2) In case of operations on animal toxins or biological substances, safety data sheets (SDS) of animal toxins or biological substances shall be provided and include types, sources, LD50, hazard, treatments, personal protective equipment, first aid in case of accidents, destruction methods, and disposal methods.

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.

Clause 29 The amounts or quantities of pathogens or animal toxins which can be produced or possessed shall take into account the readiness, biosafety, and biosecurity of operational sites.

Clause 30 Operational Site Level 3 shall have the same safety and quality systems as specified in Clause 21.

CHAPTER V
Operational Site Level 4

Clause 31 Characteristics of the place of production or possession of and operations in Operational Site Level 4 shall receive approval from the Pathogens and Animal Toxins Committee.

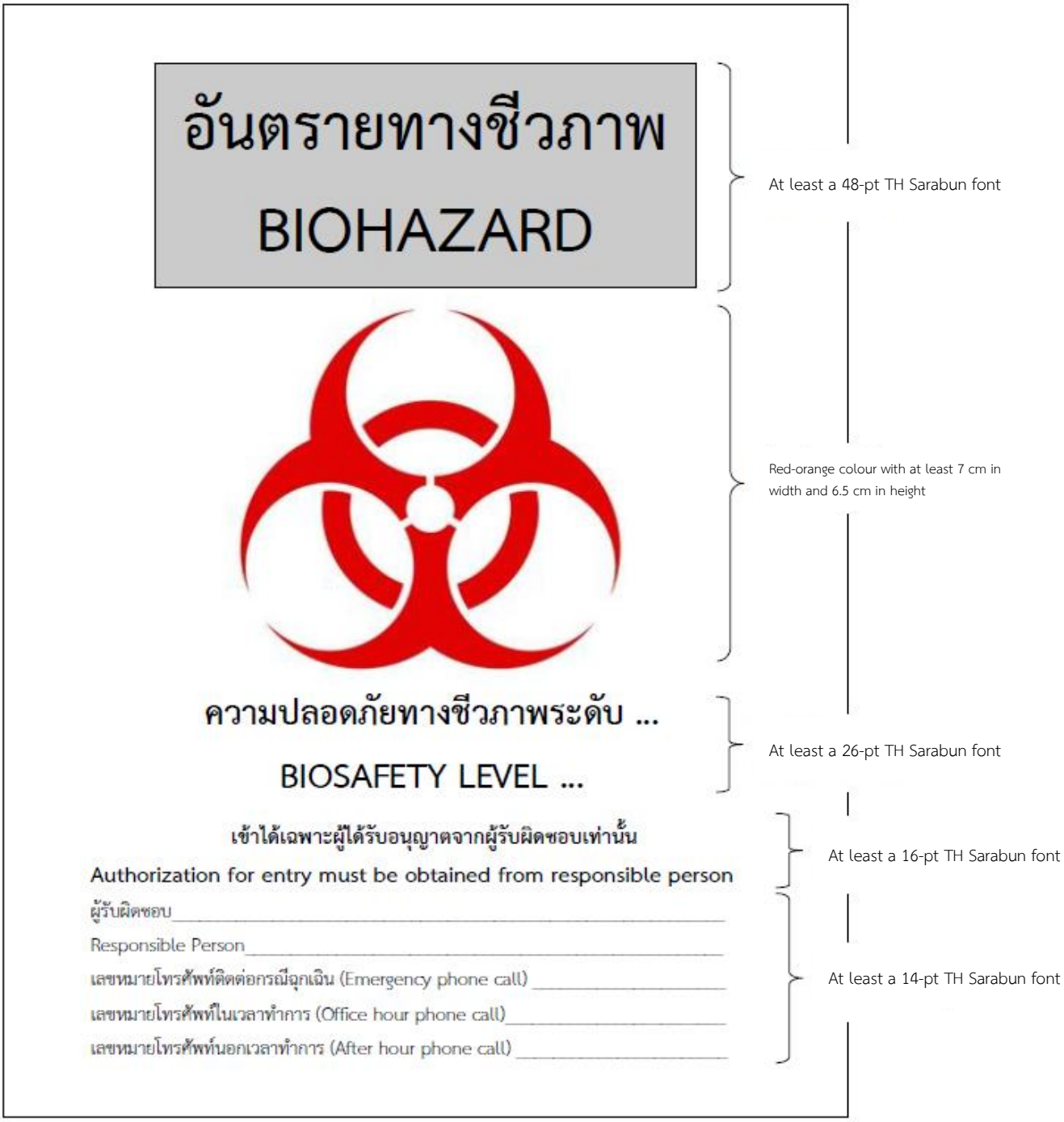
Notified on the 5th day of March B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

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.

(Unofficial Translation)

Attachment to Clause 12 of the Notification of the Ministry of Public Health Re: Characteristics of the Place of Production or Possession of and Operations on Pathogens and Animal Toxins B.E. 2563 (2020).

"Biohazard" sign shall have the following characteristics:



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.