Republic of the Philippines
HOUSEOF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 6798

INTRODUCED BY:
HONORABLE CHERYL P. DELOSO-MONTALLA
Representative, 2nd District, Zambales

AN ACT
PROVIDING FOR THE FRAMEWORK FOR THE ESTABLISHMENT AND OPERATION OF VIROLOGY LABORATORIES IN THE PHILIPPINES, CREATING FOR THE PURPOSE THE VIROLOGY SCIENCE AND TECHNOLOGY INSTITUTE OF THE PHILIPPINES (VIP), APPROPRIATING FUNDS THEREFOR AND FOR OTHER PURPOSES

EXPLANATORY NOTE

"Emerging infectious diseases caused by viruses have assumed great public health significance in the recent past. During the last three decades, almost 20 new viral pathogens have been detected. Some of these–e.g. human immunodeficiency virus (HIV) and hepatitis viruses–have already caused substantial mortality, morbidity and economic loss all over the world. The pandemic of serious acute respiratory syndrome (SARS) unequivocally demonstrated the rapidity with which new viruses can travel across the world and inflict misery. The threat of a pandemic with one of the subtypes of influenza virus is considered the greatest public health challenge in the current millennium so far."[1]

Of late, however, Corona Virus 19 took the global center stage when it put the whole world to a halt, wrought havoc to every corner of the globe, put global trade to a halt and left nations helpless amidst the virulence that it displays.

"Laboratories play a critical role in surveillance, diagnosis and monitoring of viral disease as well as in the understanding of the genetic changes in the viral genome. Laboratory tools are also essential for the diagnosis of dengue fever and chikungunya fever–two of the important vector-borne viral diseases–and for differentiating from other fevers for institution of rational and specific therapy and control measures."[2]

The "establishment of a reliable virology laboratory is a prerequisite for a strong public health response to emerging viral diseases. Unfortunately, several developing countries lack adequate capacity to diagnose viral infections."[3]

This bill is in response to the call of the Department of Science and Technology for the creation of a government-owned, biosafety level 4 laboratory which will serve as the premier virology laboratory of the country.

The proposed Virology Science and Technology Institute of the Philippines shall conduct innovative scientific researches on viral agents requiring high or maximum containment (biosafety

[1] WHO Guidelines on establishment of virology laboratory in developing countries. World Health Organization 2008
[2] Ibid.
[3] Ibid

level 2 to 4). Under this bill, research studies shall focus on vector reservoir, transmission, viral ecology, pathogenesis, pathophysiology and human, animal or plant host response of these viral pathogens. A significant goal of this bill is the development of diagnostics, vaccines and therapeutics against these viral agents.

In addition to its role in research innovation, the Institute shall also be tasked to become the reference laboratory for animal and plant virology studies. This will enable our country to be equipped with the knowledge about viral agents in plants and animals and their economic implications to agriculture.

The Institute is also mandated to become the regulatory authority for the establishment and operation of virology laboratories in the country. It shall be empowered to promulgate rules and regulations regarding virology laboratory operations.

Finally, this bill defines the minimum required standards for the establishment, operation and maintenance of virology laboratory in the country considering that internationally-accepted standards for the operation of virology laboratories are rapidly upgrading.

The establishment of the Institute as well as the other virology laboratories in the country can spur the development of genetics and bioinformatics data on pathogenic and beneficial viruses and their corresponding implications in medical management and therapeutics, genetic engineering, animal husbandry and botanical economics.

Viral pathogenic and genetic information derived from the researches in the Institute as well as in other virology laboratories in the country can be used to guide the (1) monitoring of disease outbreaks by determining the prevalent strains, (2) management of infected patients by identifying drug-resistant strains, and (3) aid in the design of vaccines and antiviral drugs by identifying molecular targets. The development of vaccines and antiviral compounds to eradicate and control the spread of viral infections is a promising area of research that may have significant socioeconomic impact."[4]

The vast array of underutilized virology research in the science industry of our country is due to our limited capacity to perform these researches. This bill is also a response to that.

Immediate passage of this bill is earnestly sought.

CHERYL P. DELOSO-MONTALLA
Representative
2nd District, Zambales

[4] http://www.icb.osaka-u.ac.jp/AnnuRep/AnnuRep35/276-292.pdf

Republic of the Philippines
HOUSEOF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 6798

INTRODUCED BY:
HONORABLE CHERYL P. DELOSO-MONTALLA
Representative, 2nd District, Zambales

AN ACT
PROVIDING FOR THE FRAMEWORK FOR THE ESTABLISHMENT AND OPERATION OF VIROLOGY LABORATORIES IN THE PHILIPPINES, CREATING FOR THE PURPOSE THE VIROLOGY SCIENCE AND TECHNOLOGY INSTITUTE OF THE PHILIPPINES (VIP), APPROPRIATING FUNDS THEREFOR AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Section 1. ***Short Title.*** – This Act shall be known as the "Virology Science and Technology Institute of the Philippines (VIP) Act"

Section 2. ***Declaration of Policy.*** – It is hereby declared the mandatory policy of the State to protect and promote the right to health of every Filipino by ensuring that they are proactively protected from diseases.

Towards this end, it is also hereby declared the policy of the State to establish a reliable national virology laboratory that shall play a critical role in surveillance, diagnosis and monitoring of viral diseases humans, plants and animals as well as in the understanding of the genetic changes in their viral genome as a prerequisite for a strong public health response to emerging, re-emerging and existing viral diseases in order to raise the level of health of the Filipino and improve their social, economic and cultural conditions.

It is hereby further declared the policy of the State that a systematic approach to the improvement of our health system requires the establishment of an institution equipped with the necessary capacity, competency, latitude and authority to decisively and scientifically respond to the demands of public health and public health emergencies, crises and situations brought about by viral infections and regulate the operation of other virology laboratories in order to prevent possible public health threats resulting from the operation of these laboratories.

Section 3. ***Definition of terms.*** - As used in this Act, the following terms shall mean:

a. *Biosafety* is the application of safety precautions that reduce a laboratory personnel's risk of exposure to a potentially infectious microbe and limit contamination of the work environment and ultimately the community;

b. *Biosafety levels* are divided into 4. Each level has specific controls for the containment of microbes and biological agents based on internationally-accepted safety standards. The primary risk that determines the levels of containment are infectivity, severity of disease transmissibility and the nature of the work conducted;

c. *Culture medium or growth medium* is a liquid or gel designed to support the growth of microorganisms.

d. *Disinfection* is the process using chemical compounds to exterminate microorganisms but does not necessarily kill all microorganisms especially resistant bacterial spores;

e. *Infectious waste* has been defined to include biological waste, cultures and stocks, pathological waste, and sharps. Each of these categories has a proper disposal method. Infectious wastes must either be incinerated or treated prior to disposal. The following are the infectious wastes:

i. *Biological waste* includes blood and blood products, excretions, exudates, secretions, suctionings and other body fluids that cannot be directly discarded into the municipal sewer system, but excludes articles contaminated with fully absorbed or dried blood. Biological waste must either be incinerated, sterilized with steam in a dedicated autoclave as described below, or treated by some other nationally recognized method which has been approved and formally adopted by the Department of Environment and Natural Resources (DENR). After treatment, biological waste may be treated as normal refuse

ii. *Cultures and stocks* include etiologic agents and associated biologicals, including specimen cultures and dishes and devices used to transfer, inoculate and mix cultures. The definition also includes wastes from the production of biologicals, serums, and discarded live or attenuated vaccines. Cultures and stocks must be treated in the same way as biological waste.

iii. *Pathological waste* includes biopsy materials, all human tissues, and anatomical parts from surgery and other procedures. It also includes carcasses and bedding from animals and plants exposed to pathogens in research, but does not include teeth or preservative agents such as formaldehyde. Pathological waste must be incinerated.

iv. *Sharps* includes needles, scalpel blades, lancets, glass tubes that could be broken during handling and syringes that have been removed from their original sterile containers. Sharps must be incinerated

f. *Kit* or test kit is a commercially packaged system of the principal or key components of an analytical method used to determine the presence of a specific analyte(s) in a given matrix (es). Test kits include directions for their use and are often self contained, complete analytical systems; but they may require supporting supplies and equipment. The key components frequently represent proprietary elements or reagents that may be readily prepared only by the producer of the kit.

g. *Personal protective equipment* consists of garments placed to protect a laboratory scientist, worker or any other person from getting infected by a viral agent. It consists of standard precautions: gloves, masks and gowns. When working with blood or airborne high infections, it shall also include face protection, goggles and masks or faces hields, gloves or coveralls, head cover and rubber boots;

h. *Reagent* is any natural or synthetic substance used in a chemical or biological reaction in order to produce, identify, or measure another substance;

i. *Risk Group 1 viruses* are microorganism that is unlikely to cause human, plant or animal disease (e.g. Adeno-associated virus (AAV) types 1-4). These viruses shall be studied in basic virology laboratories;

j. *Risk Group 2 viruses* (moderate individual risk, low community risk) are viral pathogens that can cause human, plant or animal disease but are unlikely to be a serious hazard to

laboratory workers, the community, livestock or the environment. Laboratory exposures to these group of viruses may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited. Assay systems using these viruses shall be done in biosafety level 2 laboratories. Examples include herpes viruses, foot-and- mouth disease viruses, adenoviruses and unconventional slow viruses;

k. *Risk Group 3 viruses* (high individual risk, low community risk) are viral pathogens that usually cause serious human, plant or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available against these group of viruses. Assay systems using these viruses shall be conducted in biosafety level 3 laboratories. Examples include human immunodeficiency virus (HIV), hepatitis B virus (HBV), hantaviruses, Japanese encephalitis virus (JEV), rabies, rift valley fever and yellow fever virus;

l. *Risk Group 4 viruses* (high individual and community risk) are viral pathogens that usually cause serious human, plant or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available against these group of viruses. Assay systems using these viruses shall be made in biosafety level 4 laboratories. Examples include Lassa fever, filoviruses, smallpox, Crimean-Congo haemorrhagic fever, avian influenza viruses, Nipah virus, Russian spring-summer encephalitis and Kyasanur forest disease viruses;

m. *Serology* is the scientific study or diagnostic examination of blood serum, especially with regard to the response of the immune system to pathogens or introduced substances;

n. *Smear* is a specimen for microscopic study, the material being spread thinly and unevenly across the slide with a swab or loop, or with the edge of another slide;

o. *Sterilization* is the process of exterminating all microorganisms within or outside an object or material using extreme chemical or physical;

p. *Tissue culture* refers to a collection of laboratory techniques and methods in which fragments of a tissue (human, plant or animal tissue) are introduced into a new, artificial environment, where they continue to function or grow;

q. *Virology* is the study of viruses, virus-like agents including but not limited to their taxonomy, disease-producing properties, cultivation and genetics.

CHAPTER I
VIROLOGY SCIENCE AND TECHNOLOGY INSTITUTE OF THE PHILIPPINES

Section 4. ***Creation of a Virology Science and Technology Institute of the Philippines (VIP)***. - There is hereby created a Virology Science and Technology Institute of the Philippines (VIP), hereinafter referred to as the Institute.

Section 5. ***Scope and Coverage of Virology Science and Technology***. - For purposes of this Act, the scope and coverage of the institute shall be the extensive, ground-breaking, pioneering and original research projects on the study of viruses for agricultural, industrial, clinical and environmental importance, contagious and non-contagious viral diseases from the standpoint of preventive medicine in humans, animals and plants, improving human, zoological and botanical health and welfare by suppressing infectious and non-infectious viral diseases, and clarifying and supporting the scientific background of viruses in relation to zoological, botanical and human health and medical administration of the government: *Provided*, That the Institute shall be the national reference laboratory for all zoonotic and botanical infections involving viral etiology.

Section 6. ***Authority and Responsibility***. -

a. The Institute shall be as an attached agency under the Department of Science and Technology (DOST). The DOST, in coordination with the Department of Agriculture (DA) and the Department of Health (DOH), shall promulgate policies for and exercise supervision and control over the Institute.

b. The Institute shall be headed by a Director, who shall have a rank of an undersecretary and shall be appointed by the President of the Philippines upon the recommendation of the advisory body. He shall be a qualified virologist possessing a postgraduate degree in virology with three to five years of experience in diagnostic virology. He shall have overall responsibility for the activities including the supervision of all the staff working in the Institute. In addition, he shall be directly responsible for reporting to the Secretary of Science and Technology and the President of the Philippines the results of the various diagnostic assays and research studies performed in the institute.

c. The Director shall be responsible for the implementation of policies and the immediate management of the programs and operations of the Institute. He shall also be in charge of its general institutional affairs, promote research and foster efficient assay and research activities.

d. The Director shall be assisted by a Deputy Director, who shall have a rank of an assistant secretary. He shall also be appointed by the President of the Philippines upon the recommendation of the advisory council.

Section 7. ***Powers and Functions.*** - The Institute shall be the principal laboratory of the country in providing quality virology laboratory investigations, researches and technical coordination of the entire network of the virology laboratories in the Philippines.

The Institute shall perform the following functions:

a. Conduct basic and applied research projects on zoological, botanical and human infectious, non-infectious and other intractable diseases of viral etiology with primary focus on their characterization, vector/reservoir transmission, viral ecology, clinical virology, pathogenesis, pathophysiology, and host immune response to these viral pathogens;

b. Provide reference services including all that are necessary for ensuring the assay systems for diseases of viral etiology, industrial and technological implications of virology and services involving the storing and supplying pathogenic and non-pathogenic viral agents and their vectors and hosts, standardizing reagents, preparing and supplying reference materials needed for the diagnosis and surveillance of plant, animal and human diseases, educating professional technicians, and information exchange;

c. Establish testing, reference and biosafety levels 1, 2 3, and 4 research laboratories which are fully compliant with the provisions of this Act and the internationally-accepted guidelines in the establishment and operation of the same;

d. Conduct viral disease surveillance program, collection, analysis, and feedback and distribution of information on diseases of viral etiology;

e. Comprehensively coordinate the planning and implementation of research projects, approve liaison and coordination with relevant governmental agencies, and coordinate research projects with other research institutions;

f. Provide technical advice to national authorities on the progress, needs and aspirations of the virology laboratory network in the country and to regulate the operation of the same;

g. Assist national authorities in the planning, organization and supervision of the virology laboratory network;

h. Develop technical/training material for use in laboratories in the network to enhance their quality;

i. Assess the needs and impart training to the staff of other virology laboratories in the country in quality testing for viral pathogens;

j. Validate reagents and kits that may be used nationally;

k. Validate new technologies that may become available and recommend their implementation in the country;

l. Develop minimum standards, standard operating procedures and research protocols for virology laboratories and assist virology laboratories in their implementation of the same;

m. Develop a national database on the laboratory results;

n. Organize external quality assessment schemes to periodically assess the quality of testing in networks and suggest remedial measures to those laboratories that show poor performance;

o. Undertake research to improve the quality and cost-effectiveness of virology laboratory services in the country;

p. Collaborate with the World Health Organization (WHO) and other international agencies in virology researches and technical matters pertaining to improvement of laboratories;

q. Create within the Institute various divisions that will spearhead basic and applied molecular biological research and reference activities in arbovirology, emerging and reemerging viral diseases, neurovirology, herpes virology, enteric virology, tumor virology, hepatitis virology, acute viral respiratory infections and cytokines, viral genomics and molecular genetics and biosafety control studies of viruses, among others;

r. Promulgate rules and regulations regarding the management and operation of virology laboratories in the country as well as its rules of engagement;

s. Collect fees in connection with the exercise of its regulatory powers;

t. Apply for, receive, and accept bequests, grants, and donation of funds, equipment, materials and services needed for the attainment of its objectives;

u. Provide grants, research fund, materials and equipment for the conduct of virology researches by both public and private higher education institutions;

v. Order the suspension or closure of virology laboratories and prosecution of individuals and corporations for violations of this Act;

w. Establish an editorial office of a refereed journal of virology to published it and a library which shall to collect and preserve books, journals and other reference materials in the field of virology; and

x. Perform such other related activities as may be assigned by the DOST.

Section 8. ***Organization and Personnel.*** - The Institute shall have its technical and administrative support staff as well as consultants as may be necessary. Such consultants may be

drawn from the public and private sectors on consultancy or contractual basis and shall be granted honoraria or allowances at such amounts as may be determined in accordance with existing rules and regulations.

All laboratory workers shall undergo periodic training to increase their laboratory competencies. Attendance to conferences, seminars and trainings shall be given additional service credits.

Section 9. ***Advisory Board.*** - The Institute shall have an Advisory Board composed of the following officials or their representatives:

a. The Secretary of Science and Technology, Chairman;

b. The Secretary of Health, Co-Chairman;

c. The Secretary of Agriculture, Co-Chairman; and

d. Ten (10) members from the academe who must have distinguished themselves in the field of medical virology, genomics, plant virology, animal virology, epidemiology, genetic engineering and other related disciplines and shall be appointed by the President of the Philippines.

Section 10. ***Transfer of Biomedical Research Functions***. - All functions in the Department of Health involving biomedical research in virology and in the Department of Agriculture involving animal and plant virology shall be transferred to the Institute together with their applicable appropriations, records, equipment, property and such personnel as may be necessary.

CHAPTER II
VIROLOGY LABORATORY OPERATIONS

Section 11. ***Physical structure of virology laboratories.*** - All newly constructed virology laboratories shall be located in separate, multi-storied buildings.

A virology laboratory shall be situated at the end of a corridor in a building where other laboratories are located in order to restrict entry of visitors, prevent contamination and facilitate maintaining biosafety standards.

In cases of existing laboratories, they shall be separated from other areas and facilities that are open to unrestricted staff movement within the building.

Section 12. ***Essential features of a virology laboratory.*** - Apart from the biosafety requirements, the following shall be the minimum essential features that must to be incorporated in the design of a virology laboratory:

a. Adequate space shall be provided for the safe conduct of laboratory work and for cleaning and maintenance. Designated cubicles, rooms or areas shall be available to carry out different activities, e.g. office rooms, specimen collection cubicle, specimen reception and processing room, serology laboratory, cell culture cubicle, molecular diagnostic laboratory comprising three cubicles, cold room, dark room for fluorescent microscopy, common equipment room, media preparation room, washing and sterilization section, store room, toilets and lunch room;

b. Each laboratory room shall have a space for housing a biosafety level 2 cabinet, one workbench, a sink, discard bins, wall cabinets to store consumables, a centrifuge, an incubator and a refrigerator;

c. The entire laboratory shall be climate-controlled to maintain a dust-free environment and an ambient temperature of 22–25 °C. Least cell culture cubicles, virus handling cubicles, the serology lab and the molecular biology labs shall also be air conditioned;

d. Walls, ceilings and floors shall be smooth, easy to clean, impermeable to liquids and resistant to chemicals and disinfectants normally used in the laboratory. Floors shall be slip-resistant;

e. Bench-tops shall be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat;

f. Illumination shall be adequate for all activities. Undesirable reflections and glare shall be avoided;

g. Laboratory furniture shall be sturdy. Open spaces between and under benches, cabinets and equipment shall be accessible to cleaning;

h. Storage space shall be adequate to hold supplies for immediate use and thus prevent clutter on bench tops and in aisles. Additional long-term storage space conveniently located within or outside the laboratory area shall also be provided;

i. All doors shall have vision panels, appropriate fire ratings and self-closing;

j. Facilities for storing outer garments, personal items, pantry and restrooms shall be provided outside the laboratory working area;

k. Hand-washing basins with running tap water shall be provided in each laboratory room, preferably near the exit door. A dependable supply of good quality water shall essential. There must be no cross-connections between sources of laboratory water supply and drinking water supplies;

l. There shall be reliable and adequate electricity supply and emergency lighting for safe exits. A stand-by generator shall be available at least for some equipment such as incubators, biosafety cabinets, freezers etc.; and

m. Safety systems shall cover fire, electrical emergencies, emergency shower and eyewash facilities including systems for avoiding overcrowding and too much equipment, pest control and prevention particularly rodents and arthropods and prevention of unauthorized entry into the laboratory areas.

Section 13. ***Equipment and supplies.*** - The virology laboratory shall have adequate equipment which shall take into account certain general principles, including:

a. The equipment, facilities and supplies must be designed to prevent or limit contact between the operator and the infectious material (e.g. biosafety cabinets, electronic pipetting aids, etc.);

b. The equipment and facilities must be made of materials that are impermeable to liquids, resistant to corrosion and meet internationally-accepted structural requirements;

c. The equipment and facilities must be free of sharp edges, burrs and unguarded moving parts;

d. The equipment and facilities must be designed, constructed and installed to facilitate simple operation and provide for ease of maintenance, cleaning, decontamination and certification testing; and

e. Glasswares and other breakable materials must be avoided wherever possible. Essential and desirable equipment required for a virology laboratory must conform with standards set by the Institute and internationally-recognized manuals and guidelines for virology laboratory operations.

Section 14. ***Biosafety requirements of laboratories***. - The biosafety infrastructure shall be designed on the basis of risk assessment for handling specific pathogens. The desired biosafety levels shall be established on the basis of professional judgement based on risk assessment and on internationally-accepted guidelines on the handling and management of specific viral agents.

a. In addition to the minimum essential features stipulated in Section 12, a biosafety level 2 laboratory shall have the following minimum requirements:

1. Inward airflow ventilation or controlled ventilating system;

2. On-site Autoclave: and

3. Biological safety cabinets.

b. In addition to the minimum essential features stipulated in Section 12, biosafety level 3 and 4 laboratories shall have the following minimum requirements:

1. Isolation of laboratory;

2. Room sealable for decontamination;

3. Inward airflow ventilation, controlled ventilating system and HEPA-filtered air exhaust;

4. Double-door entry;

5. Airlock;

6. Airlock with shower;

7. Anteroom;

8. Anteroom with shower;

9. Effluent treatment;

10. On site, in-laboratory and double-ended Autoclave;

11. Biological safety cabinets; and

12. Personal safety monitoring capability.

c. Biosafety level 3 and 4 laboratories must be separated from general traffic flow and accessed through an anteroom (with double door entry or basic laboratory -- Biosafety Level 2) or an airlock.

d. An autoclave must available within the facility for decontamination of wastes prior to disposal.

e. A sink with hands-free operation must available.

f. Inward directional airflow must be established and all work with infectious materials must conducted within a biological safety cabinet.

Section 15. ***Handling of viruses and specimens containing viruses.*** - Unless the recommended biosafety level facilities are available, the laboratory should not handle a particular virus. In situations where there is an outbreak of a viral illness and the required biosafety levels are not available, the specimen shall be collected and referred to the nearest laboratory that has the required biosafety laboratory. Specimens collected from patients who are suspected of suffering from viral infections caused by agents under risk groups 3 or 4 shall be directly forwarded to the reference laboratory or the Institute which has the required facilities for the handling such agents.

Section 16. ***Minimum staff requirement for a virology laboratory.*** – The minimum staff requirements for a virology laboratory shall include:

a. A qualified virologist possessing a postgraduate qualification in virology with three years of experience in diagnostic virology shall be the chief of the laboratory. He shall have overall responsibility for the activities of the laboratory and shall supervise all the staff working in it. In addition, he shall be directly responsible for reporting results of the various diagnostic assays performed in the laboratory;

b. Two junior microbiologists possessing a master's degree in medical, animal or plant microbiology with one to two years of experience in diagnostic virology. These microbiologists shall be responsible for the day-to-day operation of the laboratory including the supervision of technical staff who carry out the various diagnostic tests, stock management and procurement of laboratory supplies and diagnostic kits, quality control and quality assurance;

c. Two laboratory technologists possessing a bachelor's degree in medical technology, one to be trained in cell culture and virus isolation methods and the other to be trained in serology. The technicians shall be responsible for specimen processing, testing, laboratory safety, maintenance of laboratory records and media preparation; and

d. One or two laboratory supportive staff.

e. The duties and responsibilities of all the staff shall be clearly outlined and they shall be provided with periodic training to upgrade the knowledge and skills of the laboratory operation and management to ensure that the laboratory is abreast with contemporary diagnostic methodology as well as maintain quality in the services rendered.

Section 17. ***Use of personal protective equipment in virology laboratories.*** - Specially designed coveralls which afford protection up to the neck, facemasks or full face respirators and gloves shall be used at all times in the virology laboratory. Additional personal protective equipment shall be used when handling highly pathogenic viruses.

Section 18. ***Amenities.*** - Hand basins must be provided in each laboratory. Lockers for staff clothing must be available outside but near the laboratory rooms. Pantry/rooms for eating and drinking must be provided close to laboratory rooms.

Section 19. ***Health of staff.*** - Pre-employment medical examination for all staff shall be made. Medical monitoring for workers in biosafety level 3 and 4 laboratories shall also be conducted regularly. The scope of the monitoring shall depend on the agent being handled. Women who work with viruses must disclose their pregnancy as soon as possible. Individual evaluation of the risks involved in continued employment in the virology laboratory must also be done.

Section 20. ***Medical surveillance.*** - A system that records and follows up all cases of illness among laboratory staff to ascertain the source of infection and initiate any follow-up action shall be developed.

Section 21. ***Accidents.*** **–**

a. All accidents causing personal injury with or without exposure to infectious agents shall be reported to the supervisor or safety officer. Records should be kept of all staff sicknesses, injuries and accidents, and of x-rays and immunization;

b. A qualified first-aid provider must be present at all times in the laboratory. He/she must receive additional training in dealing with exposure to and ingestion of infectious, toxic and corrosive chemicals;

c. A well sign-posted standard first aid kit for minor injuries must be in a conspicous location inside the laboratory; and

d. Standard operating procedures for management of post-exposure prophylaxis must be in place.

CHAPTER III
LABORATORY WASTE MANAGEMENT

Section 22. ***Management of laboratory waste***. - Laboratory waste shall be segregated into colour-coded containers corresponding those for incineration, for autoclaving, normal household waste and for soiled linens.

The following practical methods shall be used in treating contaminated laboratory waste:

a. Sterilization by autoclaving using timed exposure of materials to steam above atmospheric pressure at temperatures above 100°C.

b. Chemical disinfection which is regarded as the first line defence, especially in the case of discarded bench equipment, and which should be followed by autoclaving or incineration. Chemical disinfection shall use clear sodium hypochlorite, clear phenolics, alcohols and aldehydes.

c. Incineration involves the transport of waste materials off-site for disposal using an incinerator.

d. Other internationally-accepted forms of disinfection and decontamination shall be employed in effectively preventing accidents and contamination.

Section 23. ***Infectious waste***. - Infectious wastes shall be segregated from general wastes as they need to be autoclaved or incinerated before being removed from the area in which they are generated.

Section 24. ***Routine contaminated wastes.*** – Laboratory workers shall take care to segregate their wastes from general wastes. General wastes shall be decontaminated prior to removal from the area in which they are generated. Internationally-accepted alternative means of decontamination to autoclaving or incineration may be used, provided they are effective.

Section 25. ***Management of sharps***. - All sharps shall be segregated from other wastes and placed in dedicated and labelled single-use rigid containers immediately after use. Sharps containers shall not be compacted or emptied into ordinary waste streams.

Section 26. ***Labelling of wastes.*** **-**

a. All wastes shall be identified with an appropriate type of label which shall remain attached to the waste. The label shall state the nature of waste material, the department, date, and the name of the person responsible for the waste.

b. In transporting wastes through buildings and across campus, the main consideration shall be the non-exposure of anyone to the risks from the contaminated material. Containers shall be leak-proof.

c. Wastes shall be decontaminated as far as is practical before removal from the area of generation. All laboratories shall have access to local autoclave and other appropriate decontamination facilities so as to minimize the need to transport contaminated wastes around laboratories.

CHAPTER IV
QUALITY SYSTEMS IN VIROLOGY LABORATORIES

Section 27. ***Quality systems***. - A quality system shall be instituted in all virology laboratories. It shall be comprehensive and shall cover all aspects from the decision to collect the specimen to the interpretation of results. Systematic efforts through organizational structure and efficient utilization of resources shall be used implement all the steps that shall assure generation of quality reports by the laboratory. It shall aim at consistency, reproducibility, traceability and efficaciousness of the laboratory services.

Section 28. ***Documentation.*** - Routine procedures shall be described in written Standard Operating Procedures (SOPs). They shall be reviewed regularly and modified, if necessary. The modified versions shall be signed and dated by the laboratory director. The most recent version of SOPs shall be available directly at the work place. The old versions shall be kept in the laboratory and shall be archived if required. The records shall be stored for long periods of time but shall be available for prompt retrieval. Safe archiving of all records shall be ensured.

Archiving of the source documents and other essential documents shall be done in such a way that data are kept in an integer state and can neither be lost nor altered to achieve this goal. Records of usage, maintenance and calibration shall be kept in the laboratory and shall be routinely monitored. Reports of the tests shall be released only after proper scrutiny and documentation of the scrutiny with the signature and date by the laboratory supervisor.

Section 29. ***Standard operating procedure (SOP).*** - SOP is one of the most important documents in a diagnostic laboratory. Apart from providing the complete details of how exactly a test or a procedure is carried out in a laboratory, the SOP shall provide information on specimen collection, laboratory safety instructions, purpose and limitations of the procedure, turnaround times, interpretation of results, and above all, the line of authority. The procedure manual used in the laboratory shall be complete enough in detail in order that any laboratory scientist can perform the procedure without additional information. One copy of the manual shall be readily available to bench personnel, and another copy shall be stored separately in case of accidents. A document control system shall be instituted to ensure that up-to-date document are used.

Section 30. ***Quality control checks areas.*** - The following, among others, shall be the minimum critical quality control check areas:

a. *Specimen transport*. Viral specimens held for short periods shall be refrigerated, while those for longer periods shall be frozen at –20°C or –70°C;

b. *Transport media*. The composition and type of viral transport media can affect viral isolation rates. Culture media shall be a balanced isotonic solution at physiological pH. It shall contain a substance that will stabilize the virus such as gelatin, fetal calf serum or bovine serum albumin, and antibiotics against bacteria and fungi. The swab shall be made of a material that is non-toxic to viruses, such as dacron or rayon;

c. *Smears*. Smears must contain a reasonable number of cells, be of a reasonable size, and not mixed with blood or pus in order to avoid non-specific staining;

d. *Specimens for serology*. Excessively haemolyzed, lipaemic, bacterially-contaminated, or leaking specimens shall be rejected. Sera shall be heat-inactivated depending on the tests to be performed. In the event of a specimen being rejected, the sender shall be informed, preferably by an oral report followed by a written one. Extenuating circumstances may warrant the acceptance of a substandard specimen;

e. *Tissue culture and media*. Within a given cell line, there may be significant variations in sensitivity to virus isolation which may depend on the particular cell line or clone and the passage number. Information on a particular cell line shall be recorded accurately including the source, type, passage number, confluency and cell condition. These back-up systems shall include freezing and storage of low passage cells at -70°C liquid nitrogen tanks, use of paired stock flasks or carrying of a parallel set of stock flasks using a separate set of tissue culture reagents and glassware;

Other quality control procedures that may aid in minimizing the risk of contamination shall include the exclusion of laboratory with infectious diseases from handling tissue culture, and separate laboratory apparel, reagents and glassware for tissue culture. Cell lines shall be handled separately and the cabinet shall be decontaminated in between uses;

f. *Media.* Following filter sterilization, aliquots of the media shall be taken and checked for bacteriological or fungal contamination. These samples shall be examined daily for five days and must be free from contamination. Aliquots of all other medium components such as fetal calf serum and L-glutamine shall also be checked. New lots of medium and fetal calf serum that have passed the sterility check shall be monitored for their ability to support cell growth;

g. *Reagents and kits.* Reagents and kits shall only be ordered from reputable manufacturers and dealers with reliable transportation systems. Upon receipt, the reagents shall be checked for obvious breakage or contamination. The quantity, source, lot number and date of receipt shall be entered in a logbook and the reagents stored according to the manufacturer's storage specifications. When new lots of any reagent are opened, the date shall be noted on the container. Caution shall be exercised in the case of kits as different components of a kit may require different storage conditions and have different expiration dates; and

h. *Instruments.* Laboratory instruments shall be subjected to routine preventive maintenance and checked and calibrated on a regular basis. Some of these checks may be performed by laboratory staff and entered into a logbook. The following shall be the minimum routine laboratory maintenance and performance checks on instruments:

i. *Incubators*: daily temperature, CO2 and humidity checks. Weekly decontamination of interior;

ii. *Safety cabinets*: daily air pressure check and cleaning of UV lamp. Work surface should be decontaminated after each use. Annual checks for air velocity and filter integrity and paraldehyde decontamination, as applicable;

iii. *Microscopes:* daily cleaning of objectives and stage, log of lamp usage and annual overhaul. Refrigerators and freezers: daily temperature check; annual check of compressor and refrigerant levels;

iv. *Water baths:* daily temperature checks, weekly decontamination;

v. *Refrigerated centrifuges:* weekly decontamination, annual inspection of motor, speed calibration and drive system;

vi. *Autoclaves:* daily temperature check and monthly spore strip testing;

vii. *pH meters:* single reference buffer check before each use, multiple point check monthly; and

viii. *Pipetting devices:* gravimetric volume check monthly; annual overhaul.

Section 31. ***Continuing professional education.*** – All virology laboratories shall regularly provide local and international education and training to its laboratory workers at the expense of the laboratory.

Section 32. ***Incentives of laboratory workers.*** – The DOST shall device a scheme which shall provide incentives to laboratory workers in virology laboratories whose outputs result in high-impact medical, agricultural, technological and industrial innovations.

Section 33. ***Assessment of Quality System***. - The quality system shall be assessed either through an onsite inspection (audit) or by sending known but undisclosed material to the laboratories for testing (quality assessment scheme). The latter can be done within the Institute by internal staff (internal quality assessment scheme – IQAS) or through an external agency (external quality assessment scheme – EQAS).

CHAPTER V
PENALTY PROVISIONS

Section 34. ***Penalties.*** **-**

a. In addition to acts or omissions already penalized by existing laws, the following faults or omissions shall be punishable by imprisonment of at least 12 years and 1 day to 20 years (*reclusion temporal*) or a fine of not less than five hundred thousand pesos (P500,000.00) but not more than five million pesos (P5,000,000.00), or both, such imprisonment and fine, at the discretion of the court:

i. Any person who introduces high-risk viral pathogens into the domestic environment without obtaining a permit, in violation Section 15 of this Act.

ii. Any person who refuses, interferes with, or evades an inspection for the safety control of high-risk viral pathogens;

iii. Any person who neglects to apply for permit for the operation of the virology laboratory;

iv. Any person who makes a false statement, presents false materials or documents, or intentionally omits or conceals any fact, in violation of any of the provision of this Act;

b. In addition to acts or omissions already penalized by existing laws, the following faults or omissions shall be punishable by imprisonment of at least 6 years and 1 day to 12 years (*prision mayor*) or a fine of not less than one hundred thousand pesos (P100,000.00) but not more than one million pesos (P1,000,000.00), or both, such imprisonment and fine, at the discretion of the court:

i. Any person who operates a virology laboratory in violation of Sections 11, 12, 13 and 14 of this Act.

ii. Any person who disposes laboratory waste in violation of Sections 22, 23, 24, 25 and 26 of this Act;

c. In addition to acts or omissions already penalized by existing laws, the following faults or omissions shall be punishable by imprisonment of at least 6 months and 1 day to 6 years (*prision correctional*) or a fine of not less than one hundred thousand pesos (P100,000.00) but not more than five hundred thousand pesos (P500,000.00), or both, such imprisonment and fine, at the discretion of the court:

i. Any person who operates a virology laboratory in violation of Sections 16, 17, 18, 19, 20 and 21 of this Act.

ii. Any person who operates a virology laboratory in violation of Sections 27, 28, 29, 30, 31, 32 and 33 of this Act;

Section 35. ***Joint Penalty.*** - Where a representative of a corporation, or an agent or an employee of, or any other person employed by, a corporation or individual commits any violation of the provisions of this Act in connection with the business of the corporation or individual, in addition to the punishment of such violator, the corporation or individual shall be punished by a fine under the respective provisions of Section 34.

Section 36. ***Administrative Penalty***. - In addition to acts or omissions already penalized by existing laws, the any government official or employee who, by fault or omission, violates any provision of this Act shall be perpetually disqualified from holding public office with forfeiture of benefits in favour of the State.

CHAPTER VI
OTHER PROVISIONS

Section 37. ***Congressional Overnight Committee on the Virology Science and Technology Institute of the Philippines.***— To monitor the implementation of this Act, there shall be a Congressional Oversight Committee on the Virology Science and Technology Institute of the Philippines, composed of the Chair and four (4) members of the House Committee on Science and Technology, Chair of the House Committees on Health and Agriculture and Food and the Chair and four (4) members of the Senate Committee on Science and Technology, and the Chair of the Committees on Health and Demography and Agriculture, Food and Agrarian Reform. No part of this Act shall be construed as to limit the oversight powers inherently or actually possessed by the same committees.

Section 38. ***Appropriations***. - The sum of Fifty Billion Pesos (Php 50,000,000.000.00) is hereby appropriated for implementation of the provisions of this Act: *Provided,* that such appropriation shall apply only when this Act is passed before the Institute could be given appropriation under the General Appropriations Act for the nearest upcoming year.

Such amounts as may be necessary for the operating expenses of the Institute for the current calendar year is hereby authorized to be appropriated out of any unappropriated funds in the National Treasury.

The yearly allocation equivalent to yearly requirement for virology research and operation of the Institute shall be earmarked under the General Appropriations Act.

Section 39. ***Staffing.*** — The Secretary of Science and Technology, in consultation with the Department of Budget and Management (DBM), shall determine the organizational structures, qualification standards, staffing pattern and compensation of the newly created Institute and other positions which are established under this Act in accordance with existing laws, rules and regulations.

Section 40. ***Implementing Rules and Regulations*** - The Secretary of Science and Technology shall promulgate the necessary rules and regulations within ninety (90) working days from the effectivity of this Act.

Section 41. ***Separability Clause***. — If any portion or provision of this Act is subsequently declared invalid or unconstitutional, other provisions hereof which are not affected thereby shall remain in fill force and effect.

Section 42. ***Repealing Clause***. — All other laws, acts, presidential decrees, executive orders, presidential proclamations, issuances, rules and regulations, or parts thereof which are contrary to or inconsistent with any of the provisions of this Act are hereby repealed, amended, or modified accordingly.

Section 43. ***Effectlvity.*** — This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,