Regional Plan for Containment of Poliovirus in the Americas

Regional-GAPIII

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

Regional Plan for Containment of Poliovirus in the Americas

Regional-GAPIII

Minimizing the risk of reestablishing poliovirus transmission from laboratories and other facilities in the Region of the Americas

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Washington, D.C.
2017

Regional Plan for Containment of Poliovirus in the Americas. Regional-GAPIII.

ISBN: 978-92-75-11975-4

Suggested citation: Pan American Health Organization. Regional Plan for Containment of Poliovirus in the Americas. Regional-GAPIII. Washington, D.C.: PAHO; 2017.

Cataloguing-in-Publication (CIP) data: CIP data are available at http://iris.paho.org.

Note from PAHO

Parts of the original text of the WHO GAPIII were eliminated or adapted to align the Regional plan with the recommendations of the small working group that met in April 2015 in Washington, D.C. At its 23rd meeting, the PAHO Technical Advisory Group on Vaccine-preventable Diseases endorsed the proposed Regional Plan for Containment of Poliovirus in the Region of the Americas.

Contents

Preface

Abbreviations and Acronyms

Definitions

Executive Summary

1. Introduction 1

2. Rationale 3

3. Strategy 5

Risk Elimination 5

Biorisk Management 5

4. Regional-GAPIII: Description and Implementation of Phases 9

Phase I: Preparation for containment of poliovirus 11

Phase II: Poliovirus type 2 containment period 15

Phase IIa: Containment of WPV 16

Phase IIb: Containment of OPV2/Sabin2 poliovirus 17

Phase III: Final poliovirus containment 21

Phase IIIa: Final containment of all WPV 22

Phase IIIb: Final containment of all OPV/Sabin polioviruses 23

5. Regional-GAPIII: Additional Considerations 25

6. Timetable 29

Bibliography 31

Annex A. Regional-GAPIII. Survey 33

Annex B: Regional-GAPIII. Attestation of final disposal of poliovirus materials 47

Annex C: Regional-GAPIII. National Report 49

Annex D: Regional-GAPIII. Validation form of National Containment Report 55

Preface

In December 2014, WHO published GAPIII: Global Action Plan,[a] for the main purpose of disseminating the global strategy to minimize the risk of reestablishment of circulation of poliovirus from infectious and potentially infectious samples that are stored in facilities in different sectors, including, of course, laboratories.

The actions contained in GAPIII are justified in several global decisions that began with the Global Polio Eradication Initiative (GPEI) in May 1988 (WHA41.28[b] and were updated in the recent "Polio Eradication & Endgame: Strategic Plan (PEESP) 2013-2018." (*3*)

The strategy to minimize the risk of reestablishing circulation of facility-associated poliovirus described in GAPIII[a] consists of its elimination through the destruction of materials considered to be known or probable sources of the poliovirus,[c] in all but certified, essential facilities and (*2*) proper biorisk management of these facilities through strict adherence to required safeguards.

The reasons for carrying out this task of elimination and assurance of containment in appropriate facilities are based on different scenarios that are explained below.

This document seeks to address the actions recommended by the WHO in the GAPIII guide for the containment of both wild and vaccine-derived polioviruses, as well as the PAHO's interpretation of and recommendations regarding these actions.

Andrés de Francisco, MD, PhD
Director
Family, Gender and Life Course Department

a. World Health Organization. GAPIII: Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use. 29 December 2014. Available at: http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf
b. World Health Organization. Resolution WHA41.28. Global eradication of poliomyelitis by the year 2000. Available at: http://www.who.int/ihr/polioresolution4128en.pdf
c. The specialized terms mentioned in GAPIII are defined in that document and in "Annex 1. Definitions" of this document. Their careful reading is recommended.

Acknowledgments

This version of the Regional-GAPIII is an adaptation by the Pan American Health Organization (PAHO) for the Region of the Americas of the WHO original document titled *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII)*[a] (*1*,*2*). Further considerations and annexes can be consulted directly in the original document. PAHO would like to thank all of the participants of the corresponding WorkingGroup that attended the meeting held in Washington, D.C., in April 2015 to discuss the implementation of the GAPIII plan across the Americas. Thus, we thank Gloria Rey-Benito, FGL/IM, PAHO, Washington, D.C, Sergio Diego Luis Miguel, Biosafety and Biocontainment Consultant, Argentina; Miguel Ángel Castro Jiménez, Colombian Group for Alpha Studies in Epidemiology, Colombia; Cristina Laura Lema, INEI-ANLIS "Carlos G. Malbran,"Argentina; and Edson da Silva, FIOCRUZ, Brazil.. We also thank Gloria Rey-Benito, FGL/IM, PAHO, Washington, D.C., USA, and Cuauhtémoc Ruiz-Matus, FGL/IM, PAHO, for their coordination. Finally, we thank Andrea Patricia Villalobos, consultant for FGL/IM, for her thorough review and feedback.

Abbreviations and Acronyms

AFP	Acute flaccid paralysis
BSC	Biological safety cabinet
$CCID_{50}$	Cell culture infectious dose 50%
CEN	European Committee for Standardization
CWA	CEN Workshop Agreement
DTP	Diphtheria–tetanus–pertussis
DTP3	Diphtheria–tetanus–pertussis vaccine third dose
GAP	Global Action Plan
GAPIII	Global Action Plan, third edition
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
HEPA	High-efficiency particulate arresting
HSE	Health, safety, security and environment
IPV	Inactivated polio vaccine
Sabin-IPV	Sabin-inactivated polio vaccine
Salk-IPV	WPV-inactivated polio vaccine
µm	Micrometre
MoH	Ministry of Health
NAC	National Authority of Containment
NCC	National Certification Committee
NPCC	National Polio Containment Coordinator
OPV	Oral polio vaccine
OPV2	Oral polio vaccine type 2
bOPV	Bivalent oral polio vaccine containing type 1 and type 3
mOPV	Monovalent oral polio vaccine containing one type only
mOPV2	Monovalent oral polio vaccine type 2
tOPV	Trivalent oral polio vaccine containing type 1, type 2 and type 3
PAHO	Pan American Health Organization
PEF	Poliovirus-essential facility
PPE	Personal protective equipment
PV	Poliovirus

RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
R_0	Basic reproduction rate
SOP	Standard operating procedure
VAPP	Vaccine-associated paralytic poliomyelitis
VDPV	Vaccine-derived poliovirus
aVDPV	Ambiguous vaccine-derived poliovirus
cVDPV	Circulating vaccine-derived poliovirus
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus type 2
aVDPV2	Ambiguous vaccine-derived poliovirus type 2
cVDPV2	Circulating vaccine-derived poliovirus type 2
iVDPV2	Immunodeficiency-associated vaccine-derived poliovirus type 2
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus type 1
WPV2	Wild poliovirus type 2
WPV3	Wild poliovirus type 3

Definitions

These definitions apply to the terms as used in this standard; the words may have different meanings in other contexts.

Aerosol: A dispersion of solid or liquid particles of microscopic size in a gaseous medium.

Audit: The systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Biological safety cabinets: Class II and Class III cabinets that are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens. Class II cabinets for microbiological work are partially open-fronted enclosures with air drawn around the operator into the front grille and a downward laminar flow of HEPA-filtered air that provide product protection by minimizing the chance of cross-contamination along the work surfaces of the cabinet. Class III cabinets are gas-tight enclosures with a non-opening view window, allowing access into the cabinet through a dunk tank or double-door passthrough box that is decontaminated between uses. Both supply and exhaust air are HEPA filtered or incinerated before discharge. Airflow is maintained under negative pressure.

Biorisk: Risk relating to biosafety and biosecurity where the principal hazard is a biological agent (in the case of this standard, poliovirus).

Biorisk management system: The organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining an organization's biorisk policy.

Biosafety, laboratory: The containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity, laboratory: The protection, control, and accountability for biological agents and toxins within biological facilities to prevent their unauthorized access, loss, theft, misuse, and diversion, or their intentional unauthorized release.

CCID50: A cell culture infectious dose that will infect 50% of the cell monolayers challenged with the defined inoculum.

Calibration: The correlation of the readings of an instrument with a standard.

Certification: A systematic, documented process ensuring that systems perform in accordance with available standards or applicable validation guidance.

- National certification to this standard is expected to be performed once a year through responsible national oversight bodies.

Containment: A system for confining microorganisms, organisms, or other entities within a defined space.

Contingency planning: Preparation for a future event or circumstance regarded as likely to occur, or as influencing present action.

Decontamination: A procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects.

Diagnosis: Analysis of samples for the purpose of identifying or confirming the presence of a specific agent.

Disinfection: The process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms.

Facility: Any laboratory or vaccine production unit owned or operated by any level of government, academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Facility, certifiable: A facility approved by the ministry of health or another designated national body or authority as a qualified applicant for national containment certification.

Facility, essential: A facility designated by the ministry of health or another designated national body or authority as serving critical national or international functions that involve the handling and storage of needed poliovirus infectious materials or potentially infectious materials under conditions set out in this standard.

Fumigation: The process whereby one or more chemicals are applied in the gaseous state to an enclosed space for the purpose of decontaminating the area and the items therein.

Global Certification Commission (GCC): The term commonly used to refer to the Global Commission for the Certification of the Eradication of Poliomyelitis, which has responsibility to define the parameters and processes by which polio eradication will be certified, receive and review reports of the regional commissions, and issue a final report to the Director-General of WHO certifying that global polio eradication has been achieved.

Good microbiological techniques: Technical methods designed to avoid or minimize the most common causes of laboratory injuries or work-related infections (See WHO *Laboratory biosafety manual*, *Third edition*, 2004, http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf).

Guidelines: Principles or criteria guiding or directing action.

Hazard: Any source, situation, or act with the potential for causing harm.

High-efficiency particulate arresting or high-efficiency particulate air (HEPA) filter: A filter capable of removing at least 99.97% of all particles with a mean aerodynamic diameter of 0.3 micrometers.

Inactivation: Rendering an organism inert by the application of heat or other means.

Inspection: A conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.

Legislation: The process of making laws.

National Certification Committee (NCC): The term commonly used to refer to a country's National Committee for the Certification of the Eradication of Poliomyelitis, which is responsible for certifying to the Regional Certification Commission that eradication has been achieved throughout the country.

Needed poliovirus materials: Poliovirus materials deemed needed and worth storing to ensure the continuation of essential international functions, including Salk-IPV and Sabin-IPV production, the development and storage of oral polio vaccine stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, and crucial research.

Organization: Legal entity responsible for the management of the poliovirus facility, such as a university, private company, or government agency.

Penetrations: Openings through walls, floors, or ceilings to allow for mechanical services.

Policy: The course or principle of action adopted or proposed by the responsible government entity.

Poliovirus: A picornavirus consisting of three serotypes: 1, 2, and 3. Poliovirus serotypes are further subdivided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines). Polioviruses use CD155 as the primary cellular receptor.

Poliovirus, wild:

- Wild polioviruses are naturally occurring isolates known or believed to have circulated persistently in the community.
- Vaccine-derived polioviruses (VDPV) are classified with wild polioviruses and usually demonstrate 1–15% sequence differences from the parental oral polio vaccine (OPV) strain; they may have circulated in the community (cVDPV), or have replicated for prolonged periods in immunodeficient subjects (iVDPV), or be ambiguous and of unknown origin (aVDPV).
- Attenuated strains not licensed for use as live vaccines (Cox/Lederle and Koprowski/Wistar series) are classified with wild polioviruses as their clinical properties are unproven.

Wild poliovirus materials may be (a) infectious or (b) potentially infectious.

(a) Poliovirus infectious materials, wild: These include:

- Clinical materials from confirmed wild poliovirus (including VDPV) infections.
- Environmental sewage or water samples that have tested positive for the presence of wild polioviruses.
- Cell culture isolates and reference strains of wild poliovirus
- Seed stocks and infectious materials from IPV production.
- Infected animals or samples from such animals, including human poliovirus receptor transgenic mice.
- Derivatives produced in the laboratory that has capsid sequences from wild polioviruses, unless demonstrably proven to be safer than Sabin strains. The safety of new derivatives containing wild poliovirus capsid sequences will be assessed by an expert panel, on the basis of comparison to reference Sabin strains for:
  - degree and stability of attenuation;
  - potential for person-to-person transmission; and
  - neurovirulence in animal models.
- Full-length RNA or cDNA that includes capsid sequences derived from wild poliovirus, unless viruses derived from them are demonstrably proven to be safer than Sabin strains. The safety of full-length RNA or cDNA containing wild poliovirus capsid sequences will be assessed by an expert panel convened by WHO, on the basis of comparison to reference Sabin strains for:
  - degree and stability of attenuation;
  - potential for person-to-person transmission; and
  - neurovirulence in animal models.
- Cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus.

(b) Poliovirus potentially infectious materials, wild: These include:

- Fecal or respiratory secretion samples collected for any purpose in a time and geographic area of wild poliovirus (including VDPV) circulation.
- Products of such materials from poliovirus permissive cells or animals.
- Uncharacterized enterovirus-like cell culture isolates from countries known or suspected to have circulating wild poliovirus or VDPV at the time of collection.
- Respiratory and enteric virus stocks handled under conditions where poliovirus contamination or replication is possible.

Poliovirus, Sabin (OPV/Sabin strains)**:** Attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains).

Poliovirus, OPV-like: For the laboratory network not involved in manufacture, isolates consistent with a limited period of virus excretion or person-to-person transmission, demonstrating less than 1% difference from parent OPV strains for poliovirus types 1 and 3, and less than 0.6% difference from the type 2 parent OPV strain by full Viral Protein 1 sequence homology. The phenotype of clinical and environmental OPV-like isolates need not be determined as the great majority is assumed to be of low virulence.

Sabin materials may be (a) infectious or (b) potentially infectious. The attenuated phenotype of viruses resulting from manufacture based on the OPV/Sabin seeds must be assured and cannot rely on the lack of sequence drift alone.

(a) Poliovirus infectious materials, OPV/Sabin: These include:

- Cell culture isolates and reference OPV/Sabin strains.
- Seed stocks and live virus materials from OPV production.
- Environmental sewage or water samples that have tested positive for the presence of OPV/Sabin strains.
- Fecal or respiratory secretion samples from recent OPV recipients.

- Infected animals or samples from such animals, including poliovirus receptor (PVR) transgenic mice.
- Derivatives produced in the laboratory that has capsid sequences from OPV/Sabin strains.
- Full-length RNA or cDNA that includes capsid sequences derived from OPV/Sabin strains.
- Cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains.

(b) Poliovirus potentially infectious materials, OPV/Sabin: These include:

- Fecal or respiratory secretion samples collected for any purpose in a time and geographic area of OPV use.
- Products of such materials from poliovirus permissive cells or animals.
- Respiratory and enteric virus stocks handled under conditions where OPV/Sabin strain contamination or replication is possible.

Regional Certification Commission (RCC): The term commonly used to refer to the Regional Commission for the Certification of the Eradication of Poliomyelitis, which has been established in each of the six WHO regions with responsibility to certify to the GCC that eradication has been achieved throughout all Member States of their region.

Regulation: Governmental action to control by rule or subject to restrictions.

Reproductive rate (R_0): A measure of the transmissibility of a pathogen that captures community vulnerability and virus characteristics calculated as the number of secondary infections caused by a single index case in an entirely susceptible population.

Risk: A combination of the probability of the occurrence of harm and the severity of that harm.

Risk assessment: A qualitative or semi-qualitative process undertaken by individuals with expertise in appropriate disciplines and backgrounds in response to an identified hazard.

Safeguards, primary: Containment precautions and stipulations designed to minimize the facility-associated poliovirus risks of exposing and/or infecting populations.

Safeguards, secondary: The population immunity profile consistent with minimizing the consequence of a poliovirus release from an essential containment facility, consisting of a national routine childhood immunization policy and high (>90%) national population coverage.

Safeguards, tertiary: The sanitation and hygiene conditions (good personal, domestic, and environmental hygiene standards and closed sewage systems with secondary or greater effluent treatment) that minimize the risk of reestablishing the circulation of highly transmissible wild poliovirus in the event of reintroduction.

Senior Manager (SM): The official representative of an institution with overall authority and accountability for ensuring the biosafety management of the facility.

Sharps: Devices used in the facility that is capable of cutting and/or puncturing skin (e.g., needles, scissors, glass).

Standard: A document that provides requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose.

Sterilization: A process that destroys and/or removes microorganisms and their spores.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. WHO verification of compliance with this standard may be requested for certified poliovirus-essential facilities (*14*).

Executive Summary

This working document, abbreviated as Regional-GAPIII, contains the proposed action plan to minimize the risk of reestablishing poliovirus circulation from laboratories and other facilities in the Region of the Americas, following eradication of wild poliovirus and cessation of oral polio vaccination.

This document has been agreed upon by and adapted for the Region by the small working group of the PAHO, based on the World Health Organization document *GAPIII: WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.*[a]

The Basics of WHO's GAPIII and Regional-GAPIII

The original document was developed by WHO at the global level. Only Sabin2 and WPV2 poliovirus were included in the WHO version. The PAHO adaptation includes containment of Sabin2 and wild poliovirus types 1, 2, and 3, a decision based on the widespread use of oral polio vaccine (OPV) in the countries of the Region and the fact that the last confirmed case of paralytic polio caused by wild poliovirus occurred in 1991.

The references bibliography are listed using the same numbering as in GAPIII, and all annexes cited in this document are listed in Arabic numerals as Annexes 2, 3, 4, 5, and 6 and should be consulted in the original version of GAPIII.

Annex 2: Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials
Annex 3: Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no WPV)
Annex 4: WHO verification that certified poliovirus-essential facilities comply with GAPIII
Annex 5: Risk assessment strategy
Annex 6: Biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities

The Regional-GAPIII version operationalizes WHO recommendations and includes four annexes, listed as Annexes A, B, C, and D. It was necessary to adapt the document to the regional context and have it available in English and Spanish, which are the languages used in the majority of countries and territories in the Region of the Americas.

Annex A: Regional-GAPIII. Survey
Annex B: Regional-GAPIII. Attestation of final disposal of poliovirus materials
Annex C: Regional-GAPIII. National Report
Annex D: Regional-GAPIII. Validation form of National Containment Report

1. Introduction

Launched in 1988, the Global Polio Eradication Initiative (GPEI) has been the largest international public health effort ever undertaken, involving billions of US dollars donated through GPEI partners, the dedicated efforts of governments at all levels, countless hours of volunteer services, and the immunization of billions of children with oral polio vaccine (OPV).

The Polio Eradication & Endgame Strategic Plan 2013-2018 (the Endgame Strategy) (*3*) set the goal of a polio-free world by 2018. Achieving this goal requires:

i) completion of eradication to eliminate the risk of wild poliovirus (WPV) transmission;

ii) cessation of the use of OPV to eliminate the risks of vaccine-associated paralytic poliomyelitis (VAPP), chronic immunodeficiency-associated vaccine-derived poliovirus (iVDPV), and outbreaks of circulating vaccine-derived poliovirus (cVDPV) (*4*, *5*); and

iii) Implementation of poliovirus safe-handling and containment measures to minimize the risks of a facility-associated reintroduction of virus into the polio-free community.

The first step towards cessation of trivalent OPV (tOPV) use will be the withdrawal of OPV type 2 (OPV2), which has caused over 90% of cVDPV cases since the eradication of WPV2 in 1999.

The resulting bivalent OPV (bOPV, types 1 and 3) will replace tOPV in global immunization programmes, facilitated by the introduction of ***at least*** one dose of inactivated poliovirus vaccine (IPV), composed of all three virus types.

Providing adequate IPV doses for all OPV-using countries will require both volume purchasing of existing IPV products and developing alternative low-cost IPV options (e.g. Sabin-IPV) for developing countries to meet programmatic needs.

✓ Until cessation of OPV use, bOPV ***will be the vaccine of choice*** to respond to any WPV type 1 (WPV1) and WPV type 3 (WPV3) outbreaks; while monovalent OPV type 2 (mOPV2) will be the choice for responding to type 2 outbreaks.

✓ After OPV cessation, a combination of ***type-specific mOPV*** and IPV will be used to respond to any WPV or vaccine-derived poliovirus (VDPV) outbreak.

Global consensus to stop bOPV will require international assurance that:

- the transmission of wild and vaccine-derived poliovirus has been interrupted;
- affordable, safe and effective IPVs are available;
- potential outbreaks from undetected or newly emerged cVDPV can be controlled; and
- the risk from facility-associated reintroduction of wild or OPV/Sabin polioviruses can be minimized.

The third edition of the GAPIII aligns the safe handling and containment of poliovirus infectious and potentially infectious materials with the WHO Endgame Strategy and replaces both the 2009 draft version of the third edition posted on the GPEI website and the second edition of the *WHO Global Action Plan for laboratory containment of wild polioviruses* (*6*).

Thes third edition of GAPIII will do the following:

- Describes timelines and requirements to be completed in preparation for poliovirus containment, implemented throughout the poliovirus type 2 containment period, and applied in the post-eradication and post-bOPV phase.
- Balances the need for equitable access to polioviruses, e.g. for vaccine production, throughout the poliovirus type 2 containment and post-eradication period, against the risk based on assessment findings, consequence models (*8*) and management strategies (Annexes 2 and 3).
- Establishes the long-term goal of minimizing the risk of facility-associated poliomyelitis in the post-eradication/post-bOPV era by providing continued access to safe and affordable IPV or Sabin-IPV and by reducing ***to a minimum*** the number of facilities handling and storing polioviruses while serving **critical functions** and meeting all required safeguards.

GAPIII is an evolving document, subject to revisions as new information emerges relevant to achieving the appropriate balance between community risk and the systems and controls to manage that risk.

The poliovirus "Biorisk management standard" (Annexes 2 and 3) provides the framework for facility certification based on the principles of a biorisk management system.

- This standard requires the institution/facility to understand the risks associated with its activities and to manage those risks in ways acceptable to the national and international bodies responsible for the oversight of work with polioviruses.
- National authorities are responsible for reviewing the application of these risk management standards and principles in local circumstances.
- Although Annexes 2 and 3 are written specifically for wild polioviruses and OPV/Sabin strains, respectively, as they exist at the present time, should novel strains emerge that are considered to be more attenuated, less pathogenic, and safer than OPV/Sabin strains, the evidence will be reviewed by a panel of scientific experts convened by WHO to consider the controls applicable to their containment and safe handling.

2. Rationale

When WPV circulation is interrupted, interest in immunization against polio is expected to decline and population susceptibility will increase in many parts of the world.

A reintroduction of WPV from a poliovirus facility risks the potentially serious consequences of re-establishing poliovirus transmission

When the use of OPV stops, many countries will continue high population coverage with IPV, other countries will have suboptimal IPV coverage, and still others may discontinue all national polio immunization activities.

A reintroduction of an OPV/ Sabin strain from a facility risks unrecognized virus transmission, reversion to cVDPV, and again the potential serious consequences of re-establishing poliovirus transmission (*8*).

Most countries will have no need to retain live polioviruses in the post-eradication and post-OPV era. Facility-associated risks in these countries can be eliminated by a thorough nationwide search for and destruction of all WPV and all OPV/Sabin infectious and potentially infectious materials.

Some countries will host a limited number of poliovirus facilities that serve critical international functions, including IPV and Sabin-IPV production, production and storage of mOPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, together with crucial research.

Each of these poliovirus-essential facilities should manage biorisk appropriately to minimize the risk of virus reintroduction into the community, with effective national certification and WHO verification programmes.

The risk from a poliovirus reintroduction can be minimized by:

i) locating poliovirus-essential facilities in areas with high levels of population immunity;

ii) effective acute flaccid paralysis (AFP) and environmental surveillance, supplemented by

iii) efficient public health and response capacity.

Consequences can be further minimized by working only with OPV/Sabin or alternative, more attenuated strains, which have lower basic reproduction rates ($\mathbf{R_0}$) than WPV (*8*). Minimizing the number of poliovirus-essential facilities worldwide further reduces the magnitude of the risk, facilitates national and international oversight, and strengthens the likelihood that global containment standards can be met and successfully maintained.

3. Strategy

The global strategy for minimizing poliovirus facility-associated risks consists of **risk elimination** by destroying poliovirus materials in all but certified poliovirus-essential facilities[1] and **biorisk management** of these facilities by strict adherence to required safeguards.

Risk Elimination

Risk elimination in poliovirus-non-essential facilities is achieved through the destruction, or transfer to poliovirus-essential facilities, of:

1. infectious and potentially infectious WPV materials; and
2. OPV/Sabin materials, as described below.

Destruction applies to all materials potentially contaminated with any type or strain of WPV or OPV/Sabin poliovirus, or where the presence of polioviruses cannot be ruled out, particularly with regard to untested virus stocks in facilities that in the past worked with polioviruses (*9*) and in non-polio facilities retaining valuable clinical materials potentially infected with polio or OPV/Sabin viruses.

Successful global elimination of the risk requires each country to effectively prohibit retention and subsequent acquisition of poliovirus materials in all poliovirus-non-essential facilities following global recommendations (*3*).

Biorisk Management

Biorisk management in designated poliovirus-essential facilities (Annexes 2 and 3) is achieved through the implementation of international biorisk management standards that:

1. include polio-specific containment requirements to reduce the likelihood of release of polioviruses from poliovirus-essential facilities (primary safeguards);
2. describe population immunity requirements (secondary safeguards) to minimize the consequences of the release of polioviruses from poliovirus-essential facilities; and
3. define the site-specific environmental requirements for poliovirus-essential facilities (tertiary safeguards), to further minimize the consequences of release.

1 Laboratories or polio vaccine production facilities.

Primary safeguards of containment reduce the likelihood of accidental or malicious poliovirus release from a poliovirus-essential facility and are specified in the "Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials" (Annex 2) and "Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no WPV)" (Annex 3).

Key elements include:

- facility management, which practises continuous risk assessment and strict observance; of biosafety and laboratory biosecurity procedures;
- the containment facility, which incorporates appropriate design, construction and operation principles, addressing identified biorisk;
- the immunization of facility personnel, which can reduce the risk of infection in the facility and intra- or extra-household transmission, should infection occur (*10; 11*);
- reduction in the use of WPV and the substitution with Sabin strains or further attenuated strains where possible (*10*); and
- contingency plans for potential virus release or exposure, which specify actions and assign responsibilities for the facility, the institution, the ministry of health (MoH) and other concerned government agencies.

Secondary safeguards of population immunity minimize the consequences of a poliovirus release into the community from a poliovirus-essential facility and consist of a national routine childhood polio immunization policy and the achievement of high national population coverage consistent with WHO policy (*3*) and eventual post-eradication strategies (*12*).

Tertiary safeguards of facility location minimize the consequences of the unintentional release of highly transmissible WPV by placing poliovirus-essential facilities in areas with demonstrated low poliovirus R0, i.e. in areas with closed sewage systems with a minimum of secondary treatment of effluents.

Primary and secondary safeguards are required for poliovirus-essential facilities that handle and store WPV or OPV2/Sabin2 materials during the poliovirus type 2 containment period and after cessation of bOPV use (Table 1). The potential for spread (R_0) is two to 10 times less for Sabin/OPV strains than for WPV, which reduces the risk for infection at the community level if a breach of containment occurs, and the consequences of such a breach if transmission were recognized in time (*11*).

Primary, secondary and tertiary safeguards are required for poliovirus-essential facilities that handle and store WPV materials after WPV eradication (Table 1).

✓ National certification and regular annual recertification thereafter is required for all poliovirus-essential facilities.

✓ WHO verification of compliance with GAPIII may be requested on a regular (triennial) basis.

✓ National certification supported by WHO verification provides assurance that the required safeguards are met.

TABLE 1: GAPIII containment safeguards at a glance

	Poliovirus type 2 containment period	Final poliovirus containment periods	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
1° Safeguards: Prevent infection & release of contaminated materials			
Operator protection[2]	Yes	Yes	Yes
Decontamination of materials/equipment	Yes	Yes	Yes
Dedicated effluent treatment plant	No[3]	No[3]	Yes[4]
Air/exhaust treatment	No	No	Yes[5]
2° Safeguards: Population immunity in country hosting the facility			
IPV doses	≥1	≥1	≥3
IPV coverage	= DPT3 coverage[6]	= DPT3 coverage	≥90%[7]
3° Safeguards: Environment and location			
Siting of facilities in areas with low transmission potential (R_0) for wild polioviruses	No	No	Yes

DTP3: Diphtheria–tetanus–pertussis vaccine third dose.

[2] Since the operator is considered to be one of the sources of poliovirus release from the facility, specific protection measures are required, including, for example, the use of personal protective equipment (PPE), the use of primary containment devices and vaccination

[3] Untreated release into a closed sewage system with secondary effluent treatment in the facility location (all waste from facilities, potentially containing live poliovirus, should be inactivated prior to release through adequate and validated inactivation procedures. In facilities without a dedicated effluent treatment plant, this would normally be done by applying heat or chemicals as part of a validated treatment process. Under no circumstances should raw poliovirus containing effluents be discharged to drains, unless the effluent treatment plant has been designed and validated to handle such effluents, effectively acting as part of the primary containment system).

[4] Facility effluent treatment before release into a closed sewage system with secondary or greater effluent treatment in the facility location.

[5] High-efficiency particulate arresting (HEPA) filtration on exhaust air.

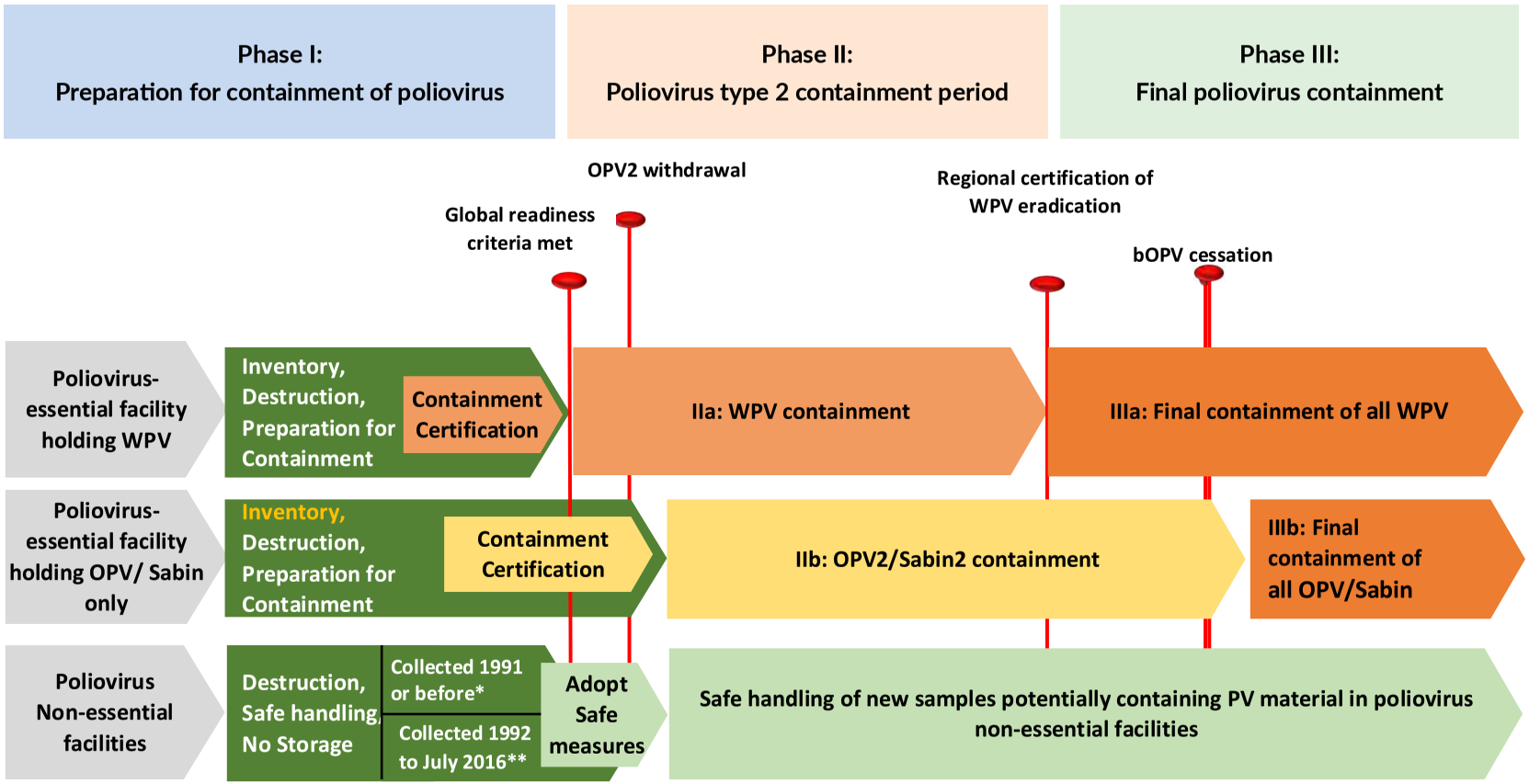
[6] Diphtheria–tetanus–pertussis vaccine third dose (DTP3) immunization coverage (*19*).

[7] Global Vaccine Action Plan 2011–2020 (*20*).

4. Regional-GAPIII: Description and Implementation of Phases

Two situations were broadly analyzed in the adaptation of the containment plan for the Americas: i) no cases of acute flaccid paralysis caused by wild poliovirus in approximately 25 years (last case in 1991) and ii) use of OPV in the majority of the national immunization programs in countries of the Region. In keeping with the Global Action Plan, the Regional Plan consists of three phases linked to national and international polio eradication milestones (Figure 1).

FIGURE 1: Phases for Containment of Poliovirus in the Region of the Americas



(*) sample was collected in 1991 or earlier it is considered as WPV potentially infectious material.

(**) sample was collected in 1992 and until 31 July 2016 (or 3 months after switch) it is considered as Sabin 2 potentially infectious material(in countries using OPV).

Source: small working group for the Regional GAPIII, April 2015

Phase I

Preparation for containment of poliovirus

Phase I consists of the following:

- National survey of laboratories or facilities. (Annex A).
- National inventory of facilities with WPV/VDPV/OPV/Sabin infectious and potentially infectious poliovirus materials. (Annex A).
- Destruction of unneeded WPV/VDPV/OPV2/Sabin2 infectious and potentially infectious poliovirus materials.
- Initiation of destruction of all unneeded WPV1 and WPV3 materials.
- Transfer of needed WPV/VDPV/OPV2/Sabin2 infectious material and potentially infectious materials to poliovirus-essential facilities.
- Inform to governments, institutions and poliovirus facilities about the upcoming need for poliovirus containment.
- Preparation for poliovirus containment.
- Certifying designated poliovirus-essential facilities.

☑ Check boxes where applicable.

During Phase I, countries shall conduct the following activities:

Activity	Done
Survey all biomedical facilities to identify those with infectious or potentially infectious WPV materials and encourage the destruction of all unneeded materials. The survey starts with the establishment of a national database of biomedical facilities that includes all facilities with the following types of laboratories: ■ poliovirus/enterovirus, ■ general virology, ■ clinical bacteriology, ■ parasitology, ■ environmental, ■ industrial (polio vaccine and general microbiological filter manufacturers and disinfectant manufacturers), or ■ any other laboratory handling and storing poliovirus. Facilities listed in the database are surveyed to confirm whether WPV infectious or potentially infectious materials are being stored;	☐
Develop a national inventory of facilities that handle and store WPV materials, and report to the PAHO Regional Certification Commission (RCC) for poliomyelitis eradication. The national inventory serves as a current record of poliovirus facilities. National inventories are assembled into regional inventories maintained by WHO regional offices.	☐
Submit reports to the RCC on the current status of the national inventory of facilities with poliovirus materials. (Annex A, B and C).	☐
Complete national surveys and inventories and submit documentation to the RCC that the Phase I survey and inventory requirements have been met. The MoH submits the complete reports on Phase I survey and inventory activities and supporting documents to the National Certification Committee for review and endorsement before submission to the RCC (Annex C).	☐

After completion of national surveys and inventories and in preparation for Phase II, all countries shall:

Activity	Done
Adopt international goals (3) for the timely destruction or containment of WPV materials and OPV2/Sabin2 materials and decide to either: ■ prohibit the retention of all GAPIII-specified poliovirus materials by any facility after achieving specific milestones; or ■ prohibit the retention of all GAPIII-specified poliovirus materials except in designated certified poliovirus essential facilities.	☐

Countries considering the need for poliovirus-essential containment facilities shall weigh the risks and benefits of such facilities in consultation with all relevant ministries (e.g. health, education, defense, environment, etc.) and the responsibilities inherent in complying with the crucial primary, secondary and tertiary safeguards. They will:

Activity	Done
Alert biomedical facilities to national policies and international agreements (*14*) pertaining to the retention of WPV materials or OPV/Sabin materials to permit orderly planning for compliance.	☐
Instruct facilities that work or have worked with poliovirus, enteroviruses, rhinovirus, rotavirus or norovirus to confirm the identity of all virus stocks, reference strains and derivatives of such viruses grown in poliovirus-permissive cell cultures to rule out the presence of poliovirus (*10*). Where and when necessary, virus stocks of uncertain histories or multiple passages must be replaced with stocks of documented authenticity from an international culture collection or from other investigators using appropriate reference techniques. Laboratories wishing to retain historic collections of clinical materials shall explore options for handling and storage arrangements with designated poliovirus-essential research and reference facilities.	☐
Request that facilities on the national inventory submit plans for compliance with poliovirus retention policies and/or regulations (*14*), including the status of materials and action timelines.	☐
Request that non-essential facilities not intending to retain poliovirus infectious or potentially infectious materials (*6*): ■ destroy unneeded WPV poliovirus (infectious and potentially infectious materials and any OPV/Sabin materials); or ■ transfer all needed poliovirus type 2 material to poliovirus-essential facilities.	☐
Request non-essential laboratory facilities that, as of Phase II, are likely to investigate new WPV, aVDPV, cVDPV, or iVDPV isolates, or new fecal or respiratory samples originating from recent OPV-using countries, to adopt and implement: ■ Safe and secure working practices based on a risk assessment and the implementation of appropriate biorisk management systems (Annex 6) ■ A non-retention policy for WPV materials as of the beginning of Phase IIa of the poliovirus type 2 containment period. ■ A non-retention policy for OPV2/Sabin2 materials as of the beginning of Phase IIb of the poliovirus type 2 containment period;	☐

If wild or Sabin2 poliovirus are isolated after the initiation of Phase IIa, the facility must immediately notify the MoH and WHO, and transfer the isolate to a designated certified poliovirus-essential facility;

Activity	Done
Notify the general biomedical laboratory community that, according to the globally endorsed Endgame Strategy (3), the retention of WPV materials will no longer be permitted in Phase IIa and the retention of OPV2/Sabin2 materials will no longer be permitted in Phase IIb, except in designated certified poliovirus-essential facilities. Facilities are fully responsible for compliance with national policies and/or regulations (*14*), including: ■ the destruction of WPV infectious and potentially infectious materials and any OPV2/Sabin2 materials ■ or the transfer of such materials to a designated poliovirus-essential facility.	☐

Facilities in the national database of biomedical laboratories with a history of performing activities that place them at risk of having potentially infectious poliovirus materials or contaminated stocks must respond to the MoH or another designated national authority documenting the absence of such materials.

Countries with plans to designate poliovirus-essential facilities shall, in addition:

Activity	Done
Request that candidate facilities assess and submit documentation demonstrating compliance with secondary and tertiary safeguards, as applicable to the type of material being held (WPV or OPV2/Sabin2 poliovirus).	☐
Implement national certification procedures to assess the compliance of poliovirus-essential facilities with provisions regarding the containment of poliovirus type 2, including primary and secondary safeguards. Designated polioviruses-essential facilities wishing to handle and store WPV materials must be fully certified before Phase II.	☐
Establish national contingency plans for responding to the potential release of or exposure to poliovirus (*15*).	☐
Request that candidate poliovirus-essential facilities[8] planning to handle and store infectious WPV materials be certified in the implementation of provisions regarding the containment of poliovirus type 2, including primary and secondary safeguards (Annex 2), before Phase II. If facilities are unable to meet the requirements, all WPV materials must be transferred to a country and facility meeting the requirements, or be destroyed.	☐
Request that candidate poliovirus-essential facilities[9] planning to handle and store only OPV2/Sabin2 materials (but no WPV materials) be certified in the implementation of provisions containment of OPV2/Sabin2 poliovirus, including primary and secondary safeguards (Annex 3), no later than three months after the switch. If facilities are unable to meet the requirements, all OPV2/Sabin2 materials must be transferred to a country and facility meeting the requirements, or be destroyed.	☐
Countries or concerned facilities may apply through their national authorities for WHO verification of poliovirus-essential facilities, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 2 or 3 (Annex 4).	☐

Preparing for the tOPV-bOPV switch

The WHA resolution (*14*) on the tOPV-bOPV switch (16) provides details on the process for implementing each step leading to OPV2 withdrawal, recall of unused tOPV and the containment of OPV2/Sabin2 polioviruses:

- Countries using tOPV shall respond to the WHA resolution (*14*) with detailed plans for compliance.
- All countries shall review or expand the Phase I institution or facility database to include new or other biomedical laboratories that might have infectious or potentially infectious OPV2/Sabin2 materials of any origin. Physicians' offices, pharmacies and health facilities that may have tOPV vials will be notified through other government channels as part of the tOPV-bOPV switch process.
- Plans and actions to prepare for the tOPV-bOPV switch continue in Phase II.

[8] Laboratories or IPV production facilities

[9] Laboratories or OPV/Sabin-IPV production facilities

Phase II

Poliovirus type 2 containment period

Phase II commences as soon as the criteria for global readiness of OPV2 withdrawal are met, and continues until certification of global WPV eradication. Readiness criteria (13) for OPV2 withdrawal. This phase has two parts, addressing the containment of WPV or OPV2/ Sabin2.

☑ Check boxes where applicable.

Phase IIa

Containment of WPV

Phase IIa commences when the criteria for global readiness for OPV2 withdrawal are met.

At the beginning of Phase IIa:

- The handling and storage of WPV materials are no longer permitted in poliovirus-non –essential facilities.
- Poliovirus non-essential laboratory facilities that are likely to investigate new WPV, aVDPV, cVDPV, or iVDPV isolates or new fecal and respiratory samples originating from recent OPV-using countries must:
  - Implement safe and secure working practices based on a risk assessment and appropriate biorisk management systems (Annex 6).
  - Not retain any WPV materials for long-term storage.
  - Immediately destroy any newly isolated WPV materials or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.
- Certified poliovirus-essential facilities[10] handling and storing WPV in Phase II must implement and be regularly reassessed with respect to the poliovirus containment" provisions, including primary and secondary safeguards, as described in Annex 2. Facilities that have not yet received formal national certification in the containment of poliovirus type 2 are no longer allowed to handle and store WPV materials.
- Countries or concerned facilities may apply through their national authorities for WHO verification of essential WPV-holding facilities, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 2 (see Annex 4).

[10] Laboratories or IPV production facilities

Phase IIb

Containment of OPV2/Sabin2 poliovirus

Moving forward with the preparations for the tOPV to bOPV switch:

Activity	Done
All countries shall notify the general laboratory community of forthcoming requirements for implementation of the "Containment of OPV2/Sabin2 poliovirus" provisions. The general laboratory community already is, or should be, aware of pending actions linked to the tOPV-bOPV switch. Facilities shall be reminded in writing of the planned date for the tOPV-bOPV switch and that national policies and regulations (*14*) pertaining to OPV2/Sabin2 poliovirus destruction or containment will be in force at that time. Communications from the MoH or another designated national authority to all biomedical laboratory facilities shall further encourage the destruction of unneeded OPV/Sabin materials. Laboratories wishing to maintain access to historic collections of clinical OPV2/Sabin2 polioviruses potentially infectious materials shall explore options for handling and storage arrangements with designated poliovirus-essential facility research and reference containment facilities.	☐

Global tOPV administration will stop (OPV2 cessation) at an effective date established by the World Health Assembly. At the effective date for the tOPV-bOPV switch (OPV2 cessation), all countries must:

Activity	Done
Recall and destroy tOPV stocks. WHO will provide specific implementation guidelines (16) for the collection and destruction of tOPV from designated collection points, health facilities or private practitioners, and national and subnational storage facilities.	☐

Phase II coincides with a period of intense VDPV surveillance and elimination. Some high-risk areas may require emergency use of monovalent OPV2 (mOPV2) vaccines to respond to emerging or reemerging VDPV2 transmission. In such areas, it may be necessary to temporarily suspend the "Containment of OPV2/Sabin2 poliovirus" provisions until the emergency is resolved.

Within six months of the switch, all countries must:

Activity	Done
Submit documentation to the RCC that the requirements regarding containment of OPV2/Sabin2 poliovirus have been met.	☐

Phase IIb commences three months after the global tOPV-bOPV switch.

As of the beginning of Phase IIb (within three months of the switch):

- The handling and storage of OPV2/Sabin2 poliovirus materials are no longer permitted in non-essential facilities.
- Non-essential laboratory facilities that are likely to investigate new fecal and respiratory samples originating from recent OPV-using countries must:
  - Implement safe and secure working practices based on a risk assessment and appropriate biorisk management systems (2).
  - Not retain any WPV or OPV2/Sabin2 materials for long-term storage.
  - Immediately destroy any newly isolated type 2 poliovirus materials or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.
- Certified poliovirus-essential facilities[11] handling and storing only OPV2/Sabin2 polioviruses (i.e., not handling and storing WPV) must implement and be regularly reassessed with respect to the "Containment of OPV2/Sabin2 poliovirus" provisions, including primary and secondary safeguards, as described in Annex 3. Sabin virus stocks of uncertain histories or multiple passages must be replaced with stocks of documented authenticity from an international culture collection or from other investigators using appropriate reference techniques to rule out possible contamination with WPV. Facilities that have not yet received formal national certification in the containment of OPV2/Sabin2 poliovirus will no longer be allowed to handle and store OPV2/Sabin2 poliovirus materials.
- Countries or concerned facilities may apply through their national authorities for WHO verification of essential OPV2/Sabin2 poliovirus-holding facilities, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 3 (see Annex 4).

[11] Laboratories or OPV/Sabin-IPV production facilities

Phase III

Final Poliovirus containment

☑ Check boxes where applicable.

Preparing for Phase III

In preparation for Phase IIIa "Final containment of all WPV", countries with essential WPV facilities shall, in addition:

Activity	Done
Implement national certification procedures to assess compliance with the "Final containment of all WPV" provisions, including primary, secondary, and tertiary safeguards.	☐
Request that poliovirus-essential facilities[12] planning to handle and store infectious WPV materials in Phase III be certified and regularly (e.g., annually) reassessed against the "Final containment of all WPV" implementation provisions, including primary, secondary, and tertiary safeguards (Annex 2), before Phase III. Facilities that have not received national certification must discontinue WPV activities until deficiencies are satisfactorily corrected and national certification is granted. If facilities are unable to meet the requirements, all WPV materials must be destroyed or transferred to a country and facility meeting the requirements before Phase III.	☐
Nationally certified essential WPV-holding facilities may be verified through WHO (Annex 4).	☐

In preparation for Phase IIIb "Final containment of all OPV/Sabin polioviruses", countries with essential OPV/Sabin facilities shall, in addition:

Activity	Done
Implement national certification procedures to assess compliance with the "Final containment of all OPV/Sabin polioviruses" provisions, including primary and secondary safeguards.	☐
Request that poliovirus-essential facilities[13] planning to handle and store OPV/Sabin or infectious Sabin-derived materials (but not WPV materials) in Phase III be certified and regularly (e.g., annually) reassessed with respect to the "Final containment of all OPV/Sabin polioviruses" implementation provisions, including primary, secondary, and tertiary safeguards (Annex 3), before bOPV cessation. Facilities that have not received national certification must discontinue OPV/Sabin poliovirus activities until deficiencies are satisfactorily corrected and national certification is granted. If facilities are unable to meet the requirements, all OPV/Sabin poliovirus materials must be destroyed or transferred to a country and facility meeting the requirements before bOPV cessation.	☐
Nationally certified essential OPV/Sabin poliovirus-holding facilities may be verified through WHO (Annex 4).	☐

Within three months of the declaration of interruption of all WPV transmission, all countries must:

Activity	Done
Submit documentation to the relevant WHO RCC that the requirements for the destruction or risk management of WPV materials in Phase II have been met.	☐

[12] Laboratories or Salk-IPV production facilities

[13] Laboratories, Sabin-IPV production, or OPV stockpile facilities

Phase IIIa

Final containment of all WPV

Phase IIIa commences when all six WHO regions have completed the certification of WPV eradication, three years after the isolation of the last WPV.

As of the beginning of Phase IIIa, certified poliovirus-essential laboratories and IPV production facilities handling and storing WPV materials must:

Activity	Done
Implement the "Final containment of all WPV" provisions, including primary, secondary, and tertiary safeguards. Facilities that have not yet received formal national certification in improved final containment of all WPV will no longer be allowed to handle and store WPV materials.	☐

Countries with essential WPV facilities shall continue to:

Activity	Done
Implement national certification procedures to regularly assess the compliance of WPV-holding facilities with the "Final containment of all WPV" provisions, including primary, secondary, and tertiary safeguards.	☐
Request that certified poliovirus- essential facilities[14] that handle and store WPV materials in Phase III be certified and regularly (e.g., annually) reassessed with respect to the "Final containment of all WPV" implementation provisions, including primary, secondary, and tertiary safeguard (Annex 2), in order to confirm their certification status. If facilities are unable to meet the requirements, all WPV materials must be destroyed or transferred to a country and facility meeting the requirements.	☐
■ Nationally certified poliovirus-essential facilities may be verified through WHO (Annex 4).	☐

[14] Laboratories or Salk-IPV production facilities

Phase IIIb

Final containment of all OPV/Sabin polioviruses

Global bOPV cessation is planned one year after the global declaration of WPV eradication.

At the effective date, all countries must:

Activity	Done
Recall and destroy bOPV stocks. WHO will provide specific implementation guidelines for the collection and destruction of bOPV from designated collection points, health facilities or private practitioners, and national and subnational storage facilities.	☐

Phase IIIb commences three months after global bOPV cessation.

As of the beginning of Phase IIIb, certified poliovirus-essential laboratories and Sabin-IPV production facilities handling and storing OPV/Sabin materials (but not WPV materials) must:

Activity	Done
Implement national certification procedures to regularly (annually) assess the compliance of OPV/Sabin-holding facilities with the "Final containment of all OPV/Sabin polioviruses" provisions, including primary, secondary, and tertiary safeguards.	☐

Countries with essential OPV/Sabin poliovirus facilities shall continue to:

Activity	Done
Implement national certification procedures to regularly (annually) assess the compliance of OPV/Sabin-holding facilities with the "Final containment of all OPV/Sabin polioviruses" provisions, including primary, secondary, and tertiary safeguards.	☐
Request that certified poliovirus-essential facilities[15] that handle and store OPV/Sabin or Sabin-derived materials (but not WPV materials) in Phase III be regularly (e.g., annually) reassessed against the "Final containment of all OPV/Sabin polioviruses" implementation provisions, including primary and secondary safeguards, in order to confirm their certification status. If facilities are unable to meet the requirements, all OPV/Sabin materials must be destroyed or transferred to a country and facility meeting the requirements. The storage of mOPV stockpiles (frozen bulk and finished products, prepared in accordance with international requirements (*15*)) and the replenishment of mOPV stockpiles of filled vaccine vials must be performed under appropriate containment conditions, based on a risk assessment approved by the competent authority.	☐
Nationally certified poliovirus-essential facilities may be verified through WHO (Annex 4).	☐

Within six months of bOPV cessation, all countries must:

Activity	Done
Submit documentation to the RCC that the requirements for the final containment of all OPV/Sabin polioviruses have been met.	☐

[15] Laboratories, Sabin-IPV production, or OPV stockpile facilities

TABLE 2: Phased implementation of poliovirus containment

Prerequisites	Phase	Begins	Target completion date	Key activities
Phase I: Preparation for containment of poliovirus				
	I: Inventory, destruction, and preparation for poliovirus containment	Ongoing	Global readiness for OPV2 withdrawal	Inventory, destruction, and preparation for poliovirus containment ✓ Survey/inventory facilities that are handling or storing infectious or potentially infectious poliovirus materials. Non-poliovirus essential facilities: ✓ Destroy unneeded poliovirus type 2 materials. ✓ Transfer needed WPV, Sabin2, and potentially infectious materials to poliovirus-essential facilities. ✓ Adopt a non-retention policy for new WPV/Sabin2 isolates, to be implemented as of Phase IIa. Poliovirus-essential facilities: ✓ Obtain national certification.
Phase II: Poliovirus type 2 containment period				
Elimination of WPV circulation Elimination of persistent cVDPV2	IIa: WPV containment period	Global readiness for OPV2 withdrawal	Regional certification of WPV eradication	**Containment of WPV** Certified poliovirus-essential WPV holding laboratory and IPV production facilities: ✓ Handle and store WPV materials in "Containment of WPV" provisions. Poliovirus non-essential facilities: ✓ Destroy remaining unneeded Sabin2 materials. ✓ Transfer needed Sabin2 materials to certified poliovirus-essential facilities. Poliovirus non-essential facilities investigating new WPV, aVDPV, cVDPV, or iVDPV isolates or new fecal and respiratory samples originating from recent OPV-using countries: ✓ Implement a non-retention policy. ✓ Destroy unneeded recently isolated poliovirus materials. ✓ Transfer needed recently isolated poliovirus materials to certified poliovirus-essential facilities.
Licensed and available bOPV Global introduction of IPV Global tOPV-bOPV switch	IIb: OPV2/ Sabin2 poliovirus containment (post-tOPV-bOPV switch)	Within three months of global tOPV-bOPV switch	Within three months of global bOPV cessation (bOPV cessation is planned one year after global certification of WPV eradication)	**Containment of OPV2/Sabin2 poliovirus** Certified poliovirus-essential OPV2/Sabin2-holding laboratories or OPV/Sabin-IPV production facilities: ✓ Handle and store OPV2/Sabin2 materials according to the "Containment of OPV2/ Sabin2 poliovirus" provisions.
Phase III: Final poliovirus containment				
Three years after isolation of last WPV	IIIa: Post-eradication	Regional certification of WPV eradication	Long-term eradication (beyond global bOPV cessation)	**Final containment of all WPV** Certified poliovirus-essential WPV-holding laboratories or IPV production facilities: ✓ Handle and store all WPV materials according to the "Final containment of all WPV" provisions.
Global bOPV cessation	IIIb: Post-bOPV cessation	Within three months of global bOPV cessation (bOPV cessation is currently planned one year after global certification of WPV eradication)	Long-term eradication (beyond global bOPV cessation)	**Final containment of all OPV/Sabin polioviruses** Certified essential OPV/Sabin-holding laboratories or IPV-Sabin production facilities: ✓ Handle and store all OPV/Sabin materials according to the "Final containment of all OPV/Sabin polioviruses" provisions.

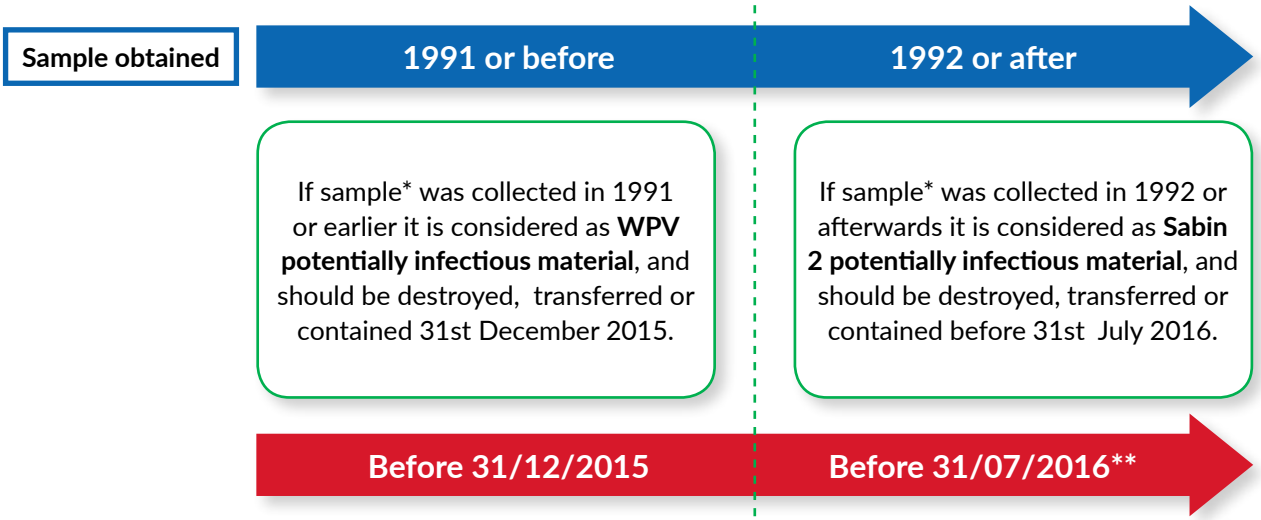
5. Regional-GAPIII: Additional Considerations

- Risk elimination in non-essential facilities is achieved through the destruction or transfer to poliovirus-essential facilities of WPV/OPV/Sabin infectious and potentially infectious materials.
- Inventory of facilities with poliovirus materials (wild, OPV/Sabin) by serotype.
- Destroy or transfer all unneeded WPV and OPV/Sabin2 infectious and potentially infectious materials.
- Containment of poliovirus type 2.
- All facilities that want to keep WPV and OPV/Sabin2 must apply to PEF's certification.
- Advance with a process of destruction of all unneeded WPV1 and WPV3 materials.
- Successful global elimination of risk requires each country to adopt a policy of no retention and subsequent acquisition of poliovirus materials in all non-essential facilities.
- Having an inventory of facilities with WPV/VDPV or OPV/Sabin infectious poliovirus materials by serotype will allow more rapid implementation of Phase III of GAPIII.
- The reason is that there may be some laboratories that keep poliovirus type 1 and/or type 3, these facilities should be considered in GAPIII Phase III.
- In this way, it is expected that not only laboratories that have applied for certification in Phase II of GAPIII will continue as the only facilities that should be considered in Phase III, for example, most Global Polio Laboratory Network (GPLN) facilities and several university and research facilities will definite to continue working with poliovirus type 1 and/or type 3.

Regional considerations for classification of potentially infectious materials:

Divisions of the historical period of collection of potentially infectious materials are set into two components (Figure 2).

FIGURE 2: Division of historic collection of poliovirus potentially infectious materials*



* Applies only to samples collected from countries in the Region of Americas.

** If the switch is confirmed by April 2016.

Laboratories that retain biological samples collected from:

- countries outside of the Americas, should review the status of the polio eradication program in the country of origin of the samples and apply consistent containment criteria as defined in the Regional-GAPIII.
- countries of the Americas Region should review the status of the national polio program and apply consistent containment criteria as defined in the Regional-GAPIII.

Decision regarding whether or not to include cerebrospinal fluid as a poliovirus potentially infectious material

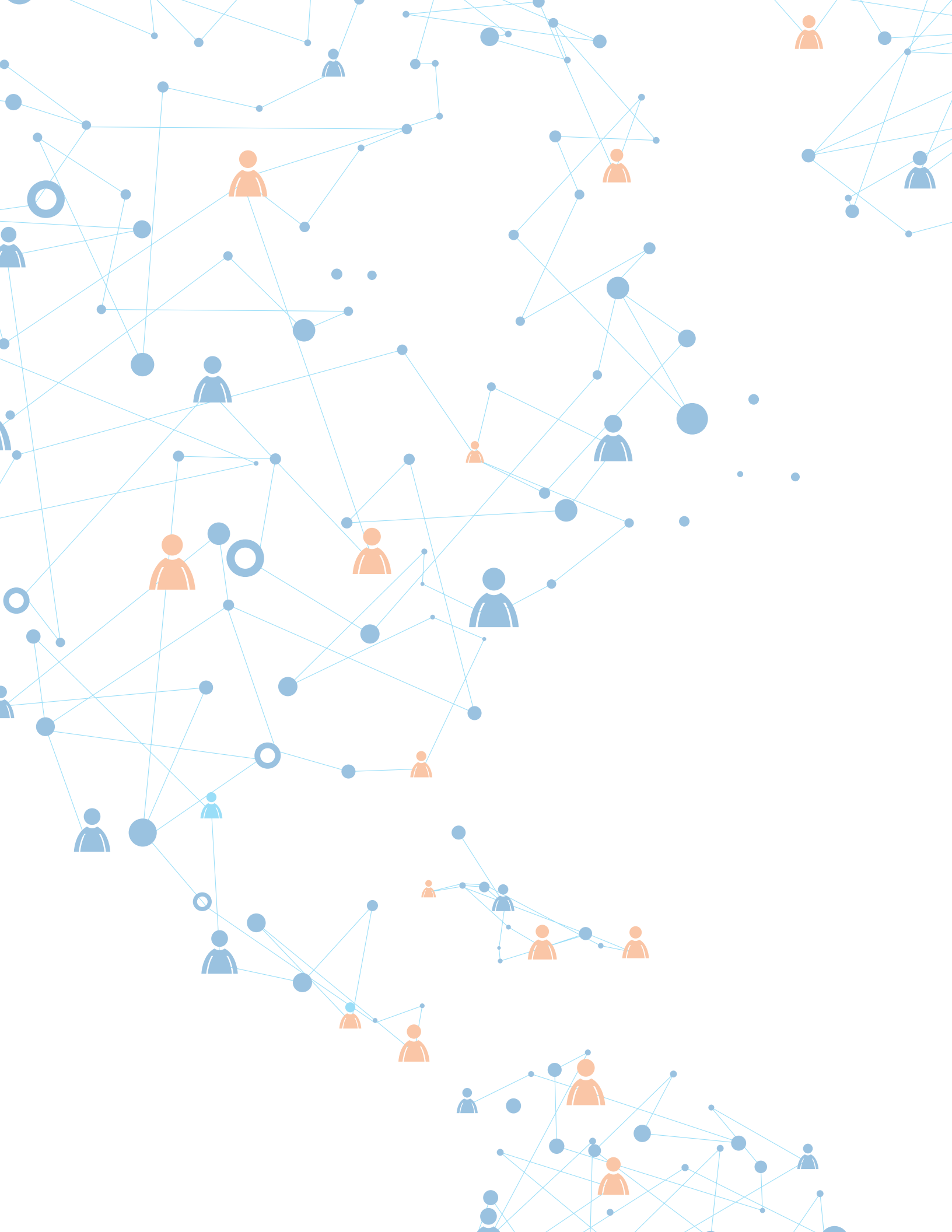
In the GAPII Phase I document, cerebrospinal fluid (CSF) was considered potentially infectious, and since GAPIII does not include CSF in its current version, the PAHO working group carried out a review of the scientific literature to assess its inclusion in the inventory survey. Although there have been published articles mentioning cases in which poliovirus was detected in CSF, it is estimated that the probability of isolation or detection of poliovirus is too low, and accordingly it was decided not to include CSF as a specimen subject to containment.

Summary of work for compliance with Regional-GAPIII:

1. Identification of laboratories with WPV or OPV/Sabin poliovirus infectious and potentially infectious materials, along with a regional survey that updates information on wild poliovirus infectious materials by serotype and provides data on handling and storing OPV/Sabin materials.
2. Decision making with respect to holding and final disposal of WPV and OPV/Sabin poliovirus infectious and potentially infectious materials. Procedures for the handling and disposal of materials should be in accordance with current national and international policies and regulations.
3. Include in the national report the name and address of the designated poliovirus-essential facility and information on the point of contact or responsible person (name, title, email address, and phone number) for each PEF.
4. Submission of the national report of containment of poliovirus to the National Certification Committee (NCC). Attach or quote resolutions or administrative acts that support the creation or delegation of the National Certification Committee (NCC) and the National Polio Containment Coordinator (NPCC).
5. Submission of the national report of containment of poliovirus to the Regional Certification Commission (RCC).
6. The RCC for the Americas is composed of experts in public health, immunization, epidemiology, pediatrics, infectious diseases, and virology, acting in their personal capacity, without direct accountability for polio eradication in their country or the Region. The RCC is responsible for assessing the achievement of the four main objectives of the Endgame, which includes the revision and validation of National/Subregional reports on poliovirus containment. The RCC uses the form found in Annex D to evaluate containment reports to ensure they meet the minimum standards. Each time the RCC finished reviewing a report, they provide detailed recommendations to the National/Subregional committee.

Countries that decide to have at least one PEF designate should:

7. Provide an official communication from the entity designated as the NAC and include the name and address of the institution and information (name, title, email address, and phone number) on the point of contact or responsible person.
8. The designated PEF should initiate the Containment Certification Scheme and the process of application to Certificate of Participation.



6. Timetable

Activity	2015 (quarter)		2016 (quarter)				2017 (quarter)	
	3rd	4th	1st	2nd	3rd	4th	1st	2nd
Designation of the National Polio Containment Coordinator (NPCC).								
List of laboratories/facilities to participate in poliovirus containment WPV/VDPV/Sabin2 survey.								
Distribution of containment of poliovirus WPV/VDPV/Sabin2 survey.								
Development of inventory of laboratories/facilities handling/storing WPV/VDPV infectious (by serotype) and potentially infectious materials.								
Destruction of unneeded WPV/VDPV infectious and potentially infectious materials.								
Transfer of WPV/VDPV infectious and potentially infectious materials to PEF.								
Containment of WPV/VDPV report, Phase IIa, reviewed by the NCC and submitted to the RCC.								
Identification of facilities to participate as PEFs.								
Designation of National Authority of Containment (NAC).								
Adoption of non-retention policy and safe measures in new samples with poliovirus potentially infectious materials.								
Elaboration of inventory of laboratories/facilities handling/storing Sabin poliovirus infectious by serotype and potentially infectious materials.								
Destruction of unneeded Sabin2 poliovirus infectious and potentially infectious materials.								
Transfer of Sabin2 poliovirus infectious and potentially infectious materials to PEF.								
Containment of OPV2/Sabin2 poliovirus report, phase IIb, reviewed by the NCC and submitted to the RCC.								
Application of PEF for containment certification scheme.								
Training of auditors for containment certification scheme								
RPLN, PEF, NAC, and NPCC.GAPIII in biorisk management training								
Implementation of requirements for PEF certification of containment.								
Initiation of PEF containment certification process.								
Certification of participation of facilities in countries that have demonstrated compliance with secondary and tertiary safeguards described in GAPIII.								

Bibliography

1. World Health Organization. Meeting of the Strategic Advisory Group of Experts on immunization, October 2014 – conclusions and recommendations. Wkly Epidemiol Rec. 2014;89: 572-3.
2. European Committee for Standardization (CEN). CEN Workshop Agreement CWA15793 – Laboratory biorisk management. Brussels: CEN; 2011 (http://www.uab.cat/doc/ CWA15793_2011, accessed 19 June 2015).
3. World Health Organization. Polio Eradication & Endgame Strategic Plan 2013-2018. Geneva: WHO; 2013.
4. Aylward RB, Sutter R, Cochi SL, Thompson KM, Jafari H, Heymann D. Risk Management in a Polio-Free World. Risk Analysis. 2006;26(6):1441–8. doi:10.1111/j.1539-6924.2006.00840.x.
5. Burns CC, Diop OM, Sutter RW, Kew OM. Vaccine-derived polioviruses. J Infect Dis. 2014;210(suppl. 1):S283–93. doi:10.1093/infdis/jiu295.
6. World Health Organization. WHO Global Action Plan for laboratory containment of wild polioviruses, Second edition. Geneva: WHO; 2004.
7. World Health Organization, Global Polio Eradication Initiative. Framework for National Policy Makers in OPV-Using Countries: Cessation of routine oral polio vaccine (OPV) use after global polio eradication. Geneva: WHO; 2005.
8. Fine PEM, Ritchie S. Consequences of release/reintroduction of polioviruses in different geographic areas after OPV cessation. Risk Analysis. 2006:1–13.
9. World Health Organization. Progress towards wild poliovirus containment in Russian Federation. Wkly Epidemiol Rec. 2005;80(49-50):426–8.
10. Dowdle WR et al. Containment of polioviruses after eradication and OPV cessation: Characterizing risks to improve management. Risk Analysis. 2006;26:1449–69.
11. Tebbens RJD, Pallansch MA, Kew OM, Caceres VM, Jafari H, Cochi SL et al. Risks of Paralytic Disease Due to Wild or Vaccine-Derived Poliovirus After Eradication. Risk Analysis. 2006;26(6):1471–1505.
12. World Health Organization. Inactivated poliovirus vaccine following oral poliovirus vaccine cessation. Wkly Epidemiol Rec. 2006;81(15):137–44.
13. World Health Organization. Resolution WHA67.38. Poliomyelitis: intensification of the global eradication initiative. In: Sixty-seventh World Health Assembly, Geneva, 19–24 May 2014. Geneva: WHO; 2014 (http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_38-en.pdf, accessed 15 June 2015).
14. World Health Organization. Resolution WHA68.3. Poliomyelitis. In: Sixty-eighth World Health Assembly, Geneva, 18–26 May 2015. Geneva: WHO; 2015 (http://apps.who.int/gb/ebwha/pdf_ files/WHA68/A68_R3-en.pdf, accessed 15 June 2015).
15. World Health Organization. Operational Framework for Monovalent Oral Poliovirus Type 2 (mOPV2) deployment and replenishment (during the endgame period). Geneva: WHO; 2015 (http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/mOPV2_ Operational_Framework.pdf, accessed 22 June 2015).
16. World Health Organization. OPV cessation – Protocol for a global coordinated switch from trivalent OPV to bivalent OPV. Geneva: WHO; 2014.
17. World Health Organization. Laboratory biosafety manual, Third edition. Geneva: WHO; 2004. (http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/, accessed 16 June 2015).
18. Dowdle WR, Birmingham ME. The biologic principles of poliovirus eradication. J Infect Dis. 1997;175 (suppl. 1):S286–92.
19. World Health Organization. Diphtheria–tetanus–pertussis (DTP3) immunization coverage (http://www.who.int/gho/immunization/dtp3/en/, accessed 16 June 2015).
20. World Health Organization. Global Vaccine Action Plan 2011–2020. Geneva: WHO; 2013 (http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/, accessed 16 June 2015).

Annex A
Regional-GAPIII. Survey

Regional-GAPIII survey: minimizing the risk of poliovirus release from facilities in the region of the Americas

The Pan American Health Organization/World Health Organization (PAHO/WHO) appreciates your participation and the participation of your institution in this survey. This form aims to collect relevant data to develop the final process of containment of poliovirus (polio) in compliance with the recommendations established in the GAPIII document (WHO, December 2014), which were revised and adapted for the Region of the Americas in GAPIII-R (PAHO, April 2015).

The questions are intended to identify and update information concerning facilities (such as laboratories, sample storage entities, etc.) and proprietary institutions and to understand the current status of handling and storing samples that can be classified as wild poliovirus (WPV), vaccine-derived poliovirus (VDPV), or oral poliovirus vaccine (OPV) infectious or potentially infectious materials. In this activity, VDPV is included within WPV.

This survey should be completed by the following facilities:

All facilities that extract, handle, or store biological samples from humans or animals under experimentation and from wastewater, drinking water, or bodies of water. These entities can be laboratories for research on clinical samples, biological laboratories, or laboratories related to public health, environmental studies, or water, as well as institutions that store samples from laboratories or research.

Structure of the survey:

This survey has an internal structure that is divided into modules labeled A1, A2, A3, B, and C.

The A1 and A2 modules must be completed by all facilities.

The A3, B, and C modules need to be completed only by selected facilities according to the instructions.

Once the survey is completed, its content must be revised and approved before it is sent. As proof of submission, it is necessary to fill out the validation module.

Some questions have detailed instructions (in italics, in a smaller font size, and in color) for easy completion.

Options to complete the survey:

1. Electronic form to respond online.

2. If you do not have permanent access to the Internet, you may download and complete a file to be uploaded online at a later time.

A1 GENERAL IDENTIFICATION

Please respond to each question.

1. Information about the proprietary institution of the laboratory or facility		
1.1 Write the name of the country in which the surveyed facility or laboratory is located		
1.2 Write the name of the proprietary institution of the laboratory or facility of interest		
1.3 Province, state, or department		
1.4 City or municipality		
1.5-1.6 Address and postal code of the institution		
1.7 Full name of the manager or director of the institution		
Email address of the manager or director of the institution	*1.8 Primary email (for example, institutional)*	
	1.9 Alternate email (if there is one)	
Phone number of the manager or director of the institution	*1.10 Primary phone number (for example, institutional)*	
	1.11 Alternate phone number (if there is one)	

2. Information about the laboratory, facility, or storage site		
2.1 Full name of the laboratory or facility		
2.2 Province, state, or department where it is located		
2.3 City or municipality where it is located		
2.4-2.5 Postal address of the laboratory/ facility		
2.6 Full name of the chief or head of the laboratory		
Email address of the chief or head of the laboratory/facility	*2.7 Primary email (for example, institutional)*	
	2.8 Alternate email (if there is one)	

A1 GENERAL IDENTIFICATION

Phone number of the chief or head of the laboratory/facility	*2.9 Primary phone number (for example, institutional)*	
	2.10 Alternate phone number (if there is one)	
3. Information about the person who completes the form		
3.1 Full name of the person responsible for completing the survey		
Position in the laboratory of the person responsible for completing the survey	*3.2 Name of position*	
	3.3 Brief description of position	
Email address of the person responsible for completing the survey	*3.4 Primary email (for example, institutional)*	
	3.5 Alternate email (if there is one)	
Phone number of the person responsible for completing the survey	*3.6 Primary phone number (for example, institutional)*	
	3.7 Alternate phone number (if there is one)	

END OF MODULE A1

A2 CLASSIFICATION OF ENTITY AND LABORATORY

4. Classification of the proprietary institution of the facility or laboratory of interest (or classification of the facility or laboratory, if it is an independent entity)

The proprietary institution of the facility *(or the laboratory itself, if it is an independent company)* is an entity... *(respond to questions 4.1 to 4.4)*

4.1 ... that belongs to the following sector: *(select only one)*	
4.1.1 Ministry of Health	☐
4.1.2 Ministry of Education	☐
4.1.3 Ministry of Defense	☐
4.1.4 Ministry of Environment	☐
4.1.5 Other	☐
4.2 ... that is classified best as: *(select only one)*	
4.2.1 Public *(functions with public resources)*	☐
4.2.2 Private *(functions with resources from partners)*	☐
4.2.3 Mixed *(public and private resources)*	☐
4.2.4 Foundation *(not-for-profit entity)*	☐
4.3 ... that has as its area of influence the following level of activities: *(select only one)*	
4.3.1 Local *(scope is restricted to municipality or city)*	☐
4.3.2 Departmental *(serves any municipality or city in the province or department)*	☐
4.3.3 National *(serves entities in any part of the country)*	☐
4.3.4 International, regional *(its scope goes beyond national borders to serve countries in the Region)*	☐
4.3.5 International, global *(its scope includes services to any country in the world)*	☐

A2 CLASSIFICATION OF ENTITY AND LABORATORY

4. Classification of the proprietary institution of the facility or laboratory of interest (or classification of the facility or laboratory, if it is an independent entity) (cont.)		
4.4 What are the primary and secondary objectives (if any) of the laboratory or facility?	*Select only one option per sector (row)*	
	Yes	**No**
4.4.1 Education	☐	☐
4.4.2 If the answer to 4.4.1 is yes, please specify which: University ☐ Other formal institution ☐		
4.4.3 Biomedical research	☐	☐
4.4.4 Health care and other areas of health aimed at the civilian population	☐	☐
4.4.5 Production laboratory (vaccines/biologicals, medicines, etc.)	☐	☐
4.4.6 Defense sector (military): clinical area	☐	☐
4.4.7 Defense sector (military): research area	☐	☐
4.4.8 Control or research of wastewater	☐	☐
4.4.9 Control or research of drinking water	☐	☐
4.4.10 Control or research of bodies of water or other natural or artificial sources	☐	☐
4.4.11 Public health laboratories/entities	☐	☐
4.4.12 Storage of biological samples or biobank	☐	☐
4.4.13 Other	☐	☐
4.4.14 If the answer to 4.4.13 is yes, please specify:		

A2 CLASSIFICATION OF ENTITY AND LABORATORY

5. Specialization of the laboratory/facility of interest	*Select only one option per sector (row)*	
	Yes	**No**
5.1 Virology	☐	☐
5.2 Bacteriology	☐	☐
5.3 Mycology	☐	☐
5.4 Parasitology	☐	☐
5.5 Pathology	☐	☐
5.6 Environmental	☐	☐
5.7 Biology	☐	☐
5.8 Other If the response is other, please specify:	☐	☐

5.9 Does the facility or laboratory have the capacity for the conservation of biological samples and water samples (from any source) at temperatures of -20°C or below (-40°C, -70°C, etc.)?	☐	☐

END OF MODULE A2

If in question 5.9 you answered **NO**, the facility does not store biological samples, then you have **FINISHED** the survey for your facility/laboratory.

For those who have finished: Thank you for taking the time to complete this survey. Please note that before sending the survey, it should be approved by the director of the proprietary institution. Please mark an ✔ in the following checkboxes to confirm your information.

Once the survey has been completed, its contents should be revised and approved before being sent.

I, _____

(first and last name of the person who completes and sends the survey),

acknowledge:

1. That the data are correct and reflect the reality of the facility/laboratory. ☐
2. That the data were revised and approved by the director of the proprietary institution. ☐

A3 TYPE OF SAMPLE/MATERIAL STORED AT 20°C OR LOWER TEMPERATURES

6. Type of sample/material stored at 20°C or lower temperature

Chart A. Type of stored frozen samples according to origin (and year collected*)

	Origin	Samples	Yes	No
Does your facility/lab currently have stored samples gathered in 1991 or earlier?	Human	6.1 fecal, for any purpose	☐	☐
		6.2 respiratory, for any purpose	☐	☐
		6.3 tissue samples (including autopsy), for any purpose**	☐	☐
	Animal	6.4 experimental animals infected with poliovirus	☐	☐
		6.5 tissues/samples from these animals	☐	☐
	Environmental***	6.6 sewage	☐	☐
		6.7 drinking water	☐	☐
		6.8 bodies of water (other sources, natural and artificial)	☐	☐
Does your facility/lab currently have stored samples gathered in 1992 or later?	Human	6.9 fecal, for any purpose	☐	☐
		6.10 respiratory, for any purpose	☐	☐
		6.11 tissue samples (including autopsy), for any purpose**	☐	☐
	Animal	6.12 experimental animals infected with poliovirus	☐	☐
		6.13 tissues/samples from these animals	☐	☐
	Environmental***	6.14 sewage	☐	☐
		6.15 drinking water	☐	☐
		6.16 bodies of water (other sources, natural and artificial)	☐	☐

* Applies only to samples collected from countries in the Region of the Americas.

** The tissue should have been collected and kept under preservation conditions that allow for the virus's viability (no formalin, paraffin, or any other fixative solution).

*** The water samples should be obtained and preserved under conditions that allow for the virus's viability.

NOTE: Laboratories that retain biological samples obtained in countries outside of the Americas should review the status of the polio eradication program in the country of origin of the samples and apply consistent containment criteria as defined in GAPIII.

A3 TYPE OF SAMPLE/MATERIAL STORED AT 20°C OR LOWER TEMPERATURES

Chart B. Type of material stored for quality control or reference

	Material	Yes	No
Poliovirus diagnostic	6.17 strains or isolates of polio/enteroviruses (regardless of origin, year, or place where obtained)	☐	☐
Polio vaccines OPV - IPV	6.18 reference strains (regardless of origin, year, or place where obtained)	☐	☐

END OF MODULE A3

Instructions on how to proceed:

If in the chart for module A3 you responded **YES**, your facility/lab stores at least one of the samples asked about (that is, you checked **YES** for at least one of the questions from 6.1 to 6.18 for one or more of the types of samples surveyed), **you should continue answering modules B and C**.

If in the chart for module A3 you responded **NO**, your facility/lab stores **none** of the samples asked about (that is, you checked **NO** for questions 6.1 to 6.16 for every type of sample surveyed), then you have **FINISHED** the survey for your facility/laboratory.

Thank you for taking the time to complete this survey. Please note that before sending the survey, it should be approved by the director of the proprietary institution. Please mark an ✔ in the following checkboxes to confirm your information.

Once the survey has been completed, its contents should be revised and approved before being sent.

I, _____

(first and last name of the person who completes and sends the survey),

acknowledge:

1. That the data are correct and reflect the reality of the facility/laboratory. ☐
2. That the data were revised and approved by the director of the proprietary institution. ☐

B INVENTORY OF BIOLOGICAL MATERIAL STORED

7-11 Types of infectious and potentially infectious poliovirus materials that are currently stored

The following boxes ask about the type(s) of sample(s) that are stored in your facility/laboratory and whether they are potentially infectious (Chart A) or infectious (Chart B).

Chart A. Potentially infectious materials by type of virus

7. Potentially infectious samples for poliovirus	*Do you have stored material?*	
	Yes	**No**
7.1 Fecal or respiratory secretion samples collected for any purpose at a time and in a geographic area with circulating wild poliovirus (including circulation of poliovirus derived from vaccines (VDPV))	☐	☐
7.2 Fecal or respiratory secretion samples collected for any purpose at a time and in a geographic area with use of OPV	☐	☐
7.3 Products of these materials used in cells or animals susceptible to poliovirus	☐	☐
7.4 Isolates of cultivated cells with cytopathic effects resembling uncharacterized enterovirus from countries that are known or suspected to have had circulation of wild poliovirus or vaccine-derived poliovirus (VDPV) at the time of collection	☐	☐
7.5 Stocks of enteric and respiratory virus handled under conditions where poliovirus replication or contamination is possible	☐	☐
7.6 Environmental samples of water or sewage that have not been tested for the presence of poliovirus	☐	☐

If you responded yes to any question from 7.1 to 7.6, specify if the potentially infectious stored material relates to WPV, Sabin, or both and mark it in the following table:

8. Potentially infectious materials by type of virus stored	
8.1 WPV	☐
8.2 Sabin	☐

B INVENTORY OF BIOLOGICAL MATERIAL STORED

Chart B. Infectious materials by type of virus

9. Samples infected with poliovirus	*Do you have stored material?*	
	Yes	No
9.1 Clinical materials of confirmed wild poliovirus infections	☐	☐
9.2 Samples of stool or respiratory secretions of recent recipients of OPV	☐	☐
9.3 Environmental samples of water or sewage that have tested positive for the presence of poliovirus	☐	☐
9.4 Isolates of cell cultures and reference strains of poliovirus	☐	☐
9.5 Seed stocks and infectious materials used in the production of IPV vaccines	☐	☐
9.6 Seed stocks and infectious materials used in the production of OPV vaccines	☐	☐
9.7 Infected animals or samples of these animals, including transgenic mice containing human poliovirus receptors (PVRs)	☐	☐
9.8 Attenuated poliovirus strains not licensed for use as live vaccines	☐	☐
9.9 Genetically modified materials that have poliovirus capsid sequences	☐	☐
9.10 Full-length cDNA or RNA that includes sequences of capsid derived from poliovirus	☐	☐
9.11 Cells persistently infected with strains of poliovirus whose sequences of capsid are derived from poliovirus	☐	☐

If you responded yes to any question from 9.1 to 9.11, specify the type of virus that is found in stored infectious materials and mark it in the following table:

10. Type of poliovirus	Type 1	Type 2	Type 3	Uncategorized
WPV	10.1 ☐	10.2 ☐	10.3 ☐	10.4 ☐
Sabin	10.5 ☐	10.6 ☐	10.7 ☐	10.8 ☐

B INVENTORY OF BIOLOGICAL MATERIAL STORED

Chart C. Summary tables of infectious and potentially infectious poliovirus materials stored in your facility/laboratory

Material	11. What is the current decision for the stored samples?*		
	A. Eliminate or destroy	B. Transfer to essential facility	C. Continue storing in the facility*
Wild poliovirus/vaccine-derived poliovirus (WPV/VDPV)			
11.1 Infectious	☐	☐	☐
11.2 Potentially infectious	☐	☐	☐
Poliovirus vaccine (OPV/Sabin)			
11.3 Infectious	☐	☐	☐
11.4 Potentially infectious	☐	☐	☐

* You must meet the criteria for a poliovirus essential facility and be certified by the national authority.

If in question 11 you responded **eliminate or destroy** all of the infectious or potentially infectious materials that you have stored, then you have **FINISHED** the survey for your facility/laboratory.

For those who have finished: Thank you for taking the time to complete this survey. Please note that before sending the survey, it should be approved by the director of the proprietary institution. Please mark an ✔ in the following checkboxes to confirm the information.

Once the survey has been completed, its contents should be revised and approved before being sent.

I, _____

(first and last name of the person who completes and sends the survey),

acknowledge:

1. That the data are correct and reflect the reality of the facility/laboratory. ☐
2. That the data were revised and approved by the director of the proprietary institution. ☐

C SELF-EVALUATION OF COMPLIANCE WITH GAP-III REQUIREMENTS

12. Self-evaluation

		Yes	No
Elements of the biological risk management system			
12.1	Does there exist a risk management system or program that includes biological risk?	☐	☐
12.2	Is the system or program periodically revised?	☐	☐
12.3	Is compliance monitored?	☐	☐
Elements of risk analysis			
12.4	Is there a formally established risk analysis for poliovirus? (practices used, where and how for every possible type of infectious material)	☐	☐
Inventory of and information regarding materials			
12.5	Is an inventory of biological material carried out?	☐	☐
12.6	Does it have traceability (entries, uses, losses, deletions, derivations or other maneuvers registered)?	☐	☐
12.7	Are control measures carried out to reconcile inventory with the material in stock?	☐	☐
Personnel and ability			
12.8	Is the staff sufficient for the task that takes place?	☐	☐
12.9	Are the personnel qualified for the functions they fulfill?	☐	☐
Microbiological techniques			
12.10	Do the "appropriate microbiological techniques" and the code of practice comply with the WHO Laboratory Biosafety Manual?	☐	☐
Personal protective equipment and clothing (PPE)			
12.11	Are there adequate personal protection items available?	☐	☐
12.12	Are there any documents that support the selection of personal protective equipment and clothing (PPE)?	☐	☐
Health care			
12.13	Is there an occupational medicine program?	☐	☐
12.14	Is there an updated vaccination schedule for staff members?	☐	☐
Decontamination, disinfection, and sterilization			
12.15	Does a procedure exist for the handling of biological residues that destroys them in a certified manner?	☐	☐
12.16	Is specific inactivation of materials verified?	☐	☐
Physical security			
12.17	Is staff access restricted?	☐	☐

C SELF-EVALUATION OF COMPLIANCE WITH GAP-III REQUIREMENTS

12. Self-evaluation (cont.)

		Yes	No
Laboratory/facility physical requirements			
12.18	Is there access through an interlocked double door?	☐	☐
12.19	Does it possess autoclave of biosafety border?	☐	☐
12.20	Is there unidirectional airflow into the laboratory?	☐	☐
12.21	Does the air extraction system have a filtration device with HEPA efficiency?	☐	☐
12.22	Is there a biological safety cabinet?	☐	☐
12.23	Is it possible to seal the laboratory for comprehensive decontamination?	☐	☐
12.24	Is there a shower in the exit circuit?	☐	☐
12.25	Is there a validated effluent treatment that receives all of the drainage from the lab?	☐	☐
Equipment maintenance			
12.26	Are there efficient resources for preventive and corrective maintenance?	☐	☐

Instructions on how to finish the survey (for facilities/laboratories that responded to modules B and C)

Thank you for taking the time to complete this survey. Please note that before sending the survey, it should be approved by the director of the proprietary institution. Please mark an ✔ in the following checkboxes to confirm your information.

Once the survey has been completed, its contents should be revised and approved before being sent.

I, _____

(first and last name of the person who completes and sends the survey),

acknowledge:

1. That the data are correct and reflect the reality of the facility/laboratory. ☐
2. That the data were revised and approved by the director of the proprietary institution. ☐

Annex B:
Regional-GAPIII. Attestation of final disposal of poliovirus materials

Attestation of final disposal of poliovirus infectious and potentially infectious materials

City	
Date	
Time	
Place	

Method used:
Sterilization or incineration technology used. Include parameters and how the sterilization (chemical or physical) or incineration process was controlled.

Source of material:
(Laboratory or institution that had the material)

Description of material:
(Type of material and quantity)

	Name	**Signature**
Accountable individual: (Laboratory head/Director)		
Witness: (High-level authority)		

Methods for disposal of poliovirus infectious or potentially infectious materials

Sterilization (use of autoclaves)	The use of moist steam under pressure is the most effective method for sterilizing laboratory materials. ■ All cultures and contaminated materials should normally be autoclaved in leak-proof containers (e.g., autoclavable color-coded plastic bags) before disposal. ■ Packaging should allow the penetration of steam. ■ After being autoclaved, the materials may be placed in transfer containers for transportation to the disposal point. ■ Autoclaves should be validated in order to ensure that sterilizing conditions are fulfilled under all loading patterns.
Incineration	Incineration is the method of choice for final disposal of contaminated waste, including carcasses of laboratory animals, preferably after autoclaving. **Incineration of materials is an alternative to autoclaving only if:** ■ the incinerator and transport to the incinerator are under laboratory control; and ■ the incinerator is equipped with an efficient means of temperature control and a secondary burning chamber.
Final disposal	The disposal of laboratory and medical waste is subject to various national regulations. In general, ash from incinerators may be treated in the same way as normal domestic waste and removed by local authorities. Autoclaved waste may be disposed of via off-site incineration or in licensed landfill sites.

Source: World Health Organization. New International Regulations on the Transport of Infectious Substances (WHO/CDS/CSR/LYO/LAB/2003). Geneva, 2003.

Annex C

Regional-GAPIII. National Report

This report needs to be accompanied with a signed letter from the NCC endorsing the report submitted.

Regional-GAPIII National Report Phase I WPV/VDPV/OPV2/Sabin2 Containment. Preparation for Poliovirus Containment

1. INTRODUCTION (brief description)

National status of polio eradication, risk of reintroduction of poliovirus since facilities and purpose of poliovirus containment

2. NATIONAL BACKGROUND

Last confirmed WPV case _____ Last confirmed VDPV case _____

Use of polio vaccines in national immunization program

OPV since _____ until _____ IPV since _____

Polio vaccine manufacturer and type of polio vaccine*

Producer _____ Type of vaccine _____

Summary of results of Phase I of containment GAPII

- Laboratories with infectious WPV materials _____
- Laboratories with potentially infectious WPV materials _____

* Refers to vaccine manufacturing plants in the country.

3. LEGAL AND POLITICAL BASIS

- Political and legislation support for the implementation of the plan
- Multi-sectoral participation

4. NATIONAL CONTAINMENT PLAN (brief description)

- Organization, assignment of responsibilities (National Certification Committee, National Polio Containment Coordinator, and National Authority for Containment required in countries with poliovirus essential facilities)
- Human and financial resources allocated
- Timeline
- Source(s) of the list of laboratories and completeness and reliability of the survey information
- Survey submission process: monitoring and receiving surveys; survey coverage, including distribution of participating laboratories
- Consolidation of information and data analysis

5. RESULTS

5.1 Total number of laboratories/facilities selected to participate: _____

5.2 Total number of surveys sent: _____

5.3 Total number of surveys received: _____

5.4 Laboratories/facilities per sector

Sector of influence for activities	Total
1. Ministry of Health/health sector	
2. Ministry of Education/education sector	
3. Ministry of Defense/defense sector	
4. Ministry of Environment/environmental sector	
5. Other sectors	

5.5 Types of laboratories with capacity for storage of biological and water samples (from any source) at temperatures of -20°C or below (-40°C, -70°C)

Specialization of laboratory/facility	Total
Virology	
Bacteriology	
Mycology	
Parasitology	
Pathology	
Environmental	
Biology	

5.6.1 Laboratory/facility with WPV/VDPV infectious poliovirus material

Name and address of laboratory/facility	Type of laboratory/ facility*	Stored WPV				Proposed disposition for the stored material		
		Type 1	Type 2	Type 3	Untyped	Eliminate or destroy	Transfer to essential facility	Continue storing in the facility[1]
	Public health laboratory		✔			Type 2 (Annex 1)		
TOTAL								

[1] If your laboratory/facility chooses to maintain poliovirus infectious material, then it must meet the criteria for a poliovirus-essential facility, as outlined in GAPIII, and be certified by your National Authority of Containment.

* Education, research, manufacturing laboratory, public health laboratory, biobank.

5.6.2 Laboratory/facility with OPV-Sabin infectious poliovirus material

Name and address of laboratory/facility	Type of laboratory/ facility*	Stored OPV-Sabin				Proposed disposition for the stored material		
		Type 1	Type 2	Type 3	Untyped	Eliminate or destroy	Transfer to essential facility	Continue storing in the facility[1]
	Manufacturing laboratory	✔	✔	✔		Type 2 (Annex 2)		Types 1 and 3
	Public health laboratory				✔	Untype (Annex 3)		
TOTAL								

[1] If your laboratory/facility chooses to maintain OPV-Sabin infectious material, then it must meet the criteria for a poliovirus-essential facility, as outlined in GAPIII, and be certified by your National Authority of Containment.

* Education, research, manufacturing laboratory, public health laboratory, biobank.

5.7.1 Laboratory/facility with WPV/VDPV potentially infectious poliovirus material

Name and address of laboratory/facility	Type of laboratory/ facility*	Proposed disposition for stored material		
		Eliminate or destroy	Transfer to essential facility	Continue storing in the facility[1]
	Education		✔ (Annex 4)	
	Research	✔ (Annex 5)	✔ (Annex 6)	
TOTAL				

[1] If your laboratory/facility chooses to maintain poliovirus potentially infectious material, then it must meet the criteria for a poliovirus-essential facility, as outlined in GAPIII, and be certified by your National Authority of Containment.

* Education, research, manufacturing laboratory, public health laboratory, biobank.

5.7.2 Laboratory/facility with OPV-Sabin potentially infectious poliovirus material

Name and address of laboratory/facility	Type of laboratory/ facility*	Proposed disposition for stored material		
		Eliminate or destroy	Transfer to essential facility	Continue storing in the facility[1]
	Public health laboratory		✔ (Annex 7)	
	Biobank		✔ (Annex 8)	
TOTAL				

[1] If your laboratory/facility chooses to maintain OPV-Sabin potentially infectious material, then it must meet the criteria for a poliovirus-essential facility, as outlined in GAPIII, and be certified by your National Authority of Containment.

* Education, research, manufacturing laboratory, public health laboratory, biobank.

5.8 List of poliovirus-essential facilities and type of materials stored

Name and address of laboratory/facility	Type of laboratory/ facility*	Stored WPV			Stored OPV-Sabin		
		Type 1	Type 2	Type 3	Type 1	Type 2	Type 3
TOTAL							

* Education, research, manufacturing laboratory, public health laboratory, biobank.

5.8.1 Activities performed to obtain certification of poliovirus-essential facilities (short description)

5.9 List of professionals involved in the implementation and development of national plan of containment (including the NPCC)

Full name	Entity	Position	Email address	Signature

6. CONCLUSIONS

Describe whether the activities undertaken and results achieved can guarantee that poliovirus containment in facilities has been fulfilled in the country

7. ANNEXES

1. Documentation on the destruction of WPV/VDPV infectious poliovirus material.
2. Documentation on the destruction OPV-Sabin infectious poliovirus material.
3. Documentation on the destruction OPV-Sabin infectious poliovirus material.
4. Letter of sending the material and letter of receiving the material in the facility.
5. Documentation on the destruction of WPV/VDPV potentially infectious poliovirus material.
6. Letter of sending the material and letter of receiving the material in the facility.
7. Letter of sending the material and letter of receiving the material in the facility.
8. Letter of sending the material and letter of receiving the material in the facility.

In addition:

- National survey format (applies to countries that created and used their own survey/questionnaire).
- Copy of the survey completed by the designated poliovirus-essential facility.
- Directives, resolutions or national binding documents.

Annex D

Regional-GAPIII. Validation form of National Containment Report

Regional-GAPIII. Validation form of National Containment Report. Phase I - GAPIII: WPV / VDPV / OPV2 / Sabin2

The purpose of this tool is to evidence and record the consistency and robustness of the information presented in the National Containment Reports Phase I - GAPIII: WPV / VDPV / OPV2 / Sabin2 of the country reports and from Caribbean Sub-region's report according to the activities described in Regional-GAPIII.

Country	
RCC Reviewer	
Date of last report submit to PAHO	

The criteria for the validation process are summarized in the analysis of the following 4 items:

1. Report submission

Report submission	Yes	No	Comments
The country has designated NPCC	☐	☐	
NPCC participated in the preparation of the report	☐	☐	
The country has designated NCC	☐	☐	
NCC is an independent body from MoH	☐	☐	
NCC reviewed and approved the report	☐	☐	
The report was submitted in the proposed template	☐	☐	

2. Follow-up on RCC and PAHO recommendations:

RCC correspondence	Yes	No	Comments
Responded previous RCC correspondence	☐	☐	

3. Completeness of the survey process:

Report define:	Yes	No	Comments
Source (s) of the list of country laboratories'	☐	☐	
Prioritized laboratories to be surveyed	☐	☐	
Cut-off date and clarity of the information presented in the report	☐	☐	

	Sent	Received	% of Response
Total surveys:			
Non-responding laboratories analysis was performed			

4. Identification and evidence of final disposal of infectious and potentially infectious materials

Infectious Material	Total of lab	# Labs – poliovirus type				# Labs according to final disposal			
		PV1	PV2	PV3	NT	Eliminate	Transfer	Store	NS
WPV/VDPV									
Sabin 2									

PV1: poliovirus1, PV2: poliovirus 2, PV3: poliovirus 3, NT: Not typed, NS: Not specified

Potentially Infectious Material	Total of lab	# Labs according to final disposal			
		Eliminate	Transfer	Store	Pending
WPV/VDPV					
Sabin 2					

Poliovirus-Essential Facilities (dPEF)

designated Poliovirus-Essential Facilities (dPEF)	Type of dPEF	Type of materials retained

RCC VALIDATION BY TYPE OF MATERIAL

Material		Previous RCC assessment review		Current RCC assessment review	
		Survey process completed *	Validation by type of material**	Survey process completed *	Validation by type of material**
Infectious	WPV/VDPV				
	Sabin 2				
Potentially Infectious	WPV/VDPV				
	Sabin 2				

***Survey process completed: Yes or no**

YES: If the process of the Phase I - GAP III survey was supported and endorsed by the NCC. If the information provided with regards to the list of laboratories, facilities selected to participate, analysis of non-responding laboratories, data analysis, consolidation of information is robust and consistent; otherwise classify as NO.

** **Validation by type of material: Approved, Not approved or No updated report**

In agreement with the Phase I - GAP III: Preparation for containment of poliovirus type 2. Country reported the identification or absence of this type of material and attached the proof of verification of the final disposal when applicable.

Comments/Observations:

RCC Reviewer signature _____ Date _____

www.paho.org/immunization

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

525 Twenty-third Street, N.W.
Washington, D.C. 20037

ISBN: 978-92-75-11975-4