FORM APPROVED
OMB NO. 0920-XXXX
EXP DATE: xx/xx/20xx

NAC
U.S. National Authority
for Containment of Poliovirus

Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire

Your facility has submitted a Certificate of Participation to the U.S. National Authority for Containment (NAC) of Poliovirus and committed to containment of poliovirus (PV) materials in accordance with the World Health Organization (WHO) Containment Certification Scheme (CCS). Poliovirus containment certification in the United States is a multi-step process overseen by the U.S. NAC.

The Poliovirus-Essential Facility (PEF) Questionnaire is used to collect additional information on the poliovirus materials held by your facility, your work activities, and facility features. Facility information for U.S. laboratories retaining poliovirus materials will be maintained by the U.S. NAC but may be shared upon request with regional and international health authorities (Pan American Health Organization (PAHO), WHO) as relevant to WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication.

Contents

This page is intentionally blank

SECTION 1: PARENT FACILITY INFORMATION

1. Application Date: _____ 2. Containment certificate(s) desired:

3. Facility Name: _____

4. Office/Dept.: _____

5. Facility Address: _____

6. Additional Offsite Address: _____

Facility Contacts	7. Name	8. Facility Title	9. Work Phone	10. Work Email
Principal Investigator				
Biosafety officer				
Institution Representative				

11. Facility Key Roles: Individuals with key roles in the biorisk management system have been designated as follows:

Role	Name
Co-investigator	
Senior manager	
Biorisk management advisor	
Scientific manager	
Occupational health professional	
Facility manager	
Security manager	
Emergency Manager	
Lab manager	
Animal care manager	
Biorisk management advisor	
Quality management system professional	

12. Poliovirus Materials* Onsite

iWPV1	iVDPV1	iOPV1	mOPV1	nOPV1
iWPV2	iVDPV2	iOPV2	mOPV2	nOPV2
iWPV3	iVDPV3	iOPV3	mOPV3	nOPV3
piWPV1	piVDPV1	piOPV1	mOPV (1 & 3)	Bivalent nOPV (1 & 3)
piWPV2	piVDPV2	piOPV2	mOPV (1, 2, & 3)	Bivalent nOPV (1, 2, & 3)
piWPV3	piVDPV3	piOPV3		
Other/new poliovirus strains (e.g., S19)				
Other				

** Prefix of 'i' indicates infectious material whereas 'pi' indicates potentially infectious materials; 'm' indicates monovalent vaccine; 'n' indicates a novel vaccine.*

13. Poliovirus Strains

VirusType	Strain
Example: WPV1	Mahoney

14. Poliovirus funding source(s):

15. Justification for critical national or international function:

SAFEGUARDS

16. Immunization/Secondary safeguards (Pol3 Immunization coverage estimates):

17. Population and demographic characteristics within a 100 km radius of PEF, including any pockets of susceptible individuals:

18. Occupational health requirements for PV containment areas (check all that apply):

A. Staff			
☐	PV childhood immunization records	☐	Medical clearance for respirator
☐	Adult IPV booster	☐	Respirator fit test
☐	PV proof of immunity	☐	Tuberculosis skin test
☐	Other required immunizations:		
☐	Other:		

B. Visitors			
☐	PV childhood immunization records	☐	Medical clearance for respirator
☐	Adult IPV booster	☐	Respirator fit test
☐	PV proof of immunity	☐	Tuberculosis skin test
☐	Other required immunizations:		
☐	Other:		

19. Environmental/Tertiary safeguards (closed sanitation system with at least secondary or greater treatment of PEF effluents):

SECURITY SYSTEMS AND PRACTICES

20. Facility is located on a secure site with perimeter control (e.g., perimeter fence) ..... ☐
21. Facility perimeter is subject to constant monitoring (e.g., through use of alarms, security personnel) ..... ☐
22. Facility ensures two-person system with second individual within the containment perimeter or in close proximity during PV work ☐
23. Facility building(s) are equipped with intrusion detection system where PV containment areas are located ..... ☐
24. Facility building(s) are equipped with video surveillance where PV containment areas are located ..... ☐
25. Facility has a security plan or procedure that identifies appropriate security controls for PV as determined by risk assessment ☐
26. Facility has defined and implemented a personnel reliability policy ..... ☐
    - 26a. Personnel reliability policy requires verification of references ..... ☐
    - 26b. Personnel reliability policy requires verification of criminal history ..... ☐
    - 26c. Personnel reliability policy requires verification of education ..... ☐
27. Visitor Identification Required ..... ☐

BIORISK MANAGEMENT SYSTEM

28. Management systems and practices, regulations, or standards implemented for PV work:

☐ Clinical Laboratory Improvement Amendments (CLIA) ☐ Good Laboratory Practice (GLP)

☐ International Standardards Organization (ISO) ☐ Good Microbiological Practice (GMP)

☐ Quality Management System (QMS) (if selected, briefly describe):

☐ Other:

29. Management review process and frequency for PEF:

30. Internal audit process and frequency for PEF:

31. Risk assessment process for PV work and PEF site (e.g., facility, security, emergency response):

32. PV work has been reviewed by institutional biosafety committee or equivalent: ..... ☐ Yes ☐ No ☐ N/A

33. PV animal work has been reviewed by institutional animal care and use committee or equivalent: ..... ☐ Yes ☐ No ☐ N/A

34. Notification and coordination with state and local agencies that support emergency response plans for the PEF:

GAP ELEMENTS

35. ICC/CC Facility: Indicate PEF processes aligned to GAP elements (check all that apply):

A. Laboratory processes					
☐	Planning	☐	Equipment	☐	Shipping
☐	Purchasing	☐	Testing	☐	Decontamination
☐	Personnel	☐	Quality Assurance/Quality Control	☐	Management Review
☐	Facilities	☐	Inventory		
☐	Other:				

B. Support processes					
☐	Quality Managment System (QMS)	☐	Occupational Health	☐	Maintenance
☐	Environmental Health and Safety	☐	Security	☐	Contractors/Supplies
☐	Training	☐	Emergency Response		
☐	Other:				

35. ICC/CC Facility: Facility has identified nonconformities to the following GAP element(s) that will be resolved during an interim certificate of containment (ICC-NCs)? ..... ☐ Yes ☐ No

If yes, check all that apply:

☐ Element 1 - Biorisk Management System	☐ Element 8 - Facility Physical Requirements
☐ Element 2 - Risk Assessment and Control	☐ Element 9 - Equipment & Maintenance
☐ Element 3 - Worker Health Programme	☐ Element 10 - Poliovirus Inventory & Information
☐ Element 4 - Competency/Training	☐ Element 11 - Waste Mgnt, Decon, Disinfect, & Sterilize
☐ Element 5 - Good Microbiological Practice Procedure	☐ Element 12 - Transport Procedures
☐ Element 6 - Clothing & Personal Protective Equipment	☐ Element 13 - Emer Response & Contingency Planning
☐ Element 7 - Security	☐ Element 14 - Accident/Incident Investigation

SECTION 2: LABORATORY/STORAGE AREA INFORMATION

Information regarding laboratory and storage areas including infrastructure and operation management. If more than one area was declared, information is displayed for each.

Location 1 Building: Room:

1. Campus:

1a. Room Use: ..... ☐ Lab space ☐ Storage

1b. Dedicated space: ..... ☐ Yes ☐ No

1c. Location used during what phase of CCS? ...(CP Only/ICC/CC).....

1d. PV materials used in this space:

iWPV1	iVDPV1	iOPV1	mOPV1	nOPV1
iWPV2	iVDPV2	iOPV2	mOPV2	nOPV2
iWPV3	iVDPV3	iOPV3	mOPV3	nOPV3
piWPV1	piVDPV1	piOPV1	mOPV (1 & 3)	Bivalent nOPV (1 & 3)
piWPV2	piVDPV2	piOPV2	mOPV (1, 2, & 3)	Bivalent nOPV (1, 2, & 3)
piWPV3	piVDPV3	piOPV3		
Other/new poliovirus strains (e.g., S19)				
Other				

2. Building construction date:

3. Room construction/renovation date:

4. PV facility support system renovations since construction:

5. Total area of the suite/room (sq ft):

6. Designated safety level for the PV containment area (e.g., BSL-2, A/BSL-3):

7. Number of rooms in the containment area:

8. Number of individuals with **direct access** to poliovirus material:

9. Number of individuals with access to the containment area:

10. Poliovirus immunization verified for all individuals entering containment area:

11. Floor plan on file with NAC: ..... ☐ Yes ☐ No

Note: Floor plan for each room should include as applicable: points of entry and/or egress for personnel, locations of equipment including but not limited to: sink, shower, autoclave, BSC including type (e.g., Class II, Type A2; Class III). Note, for equipment (e.g., autoclave, emergency shower) located outside of the containment laboratory, provide separate floor plan showing location of equipment relative to the PV2 laboratory.

12. PV laboratory personal protective equipment (PPE):

☐ Gloves ☐ Scrubs ☐ Eye/face protection ☐ Dedicated lab shoes

☐ Disposable wrap-around gown ☐ Safety glasses ☐ Respirator ☐ PAPR

☐ Tyvek suit or coverall ☐ Face or surgical mask ☐ Shoe Covers

☐ Other:

13. Will facility supply PPE to visitors for entry to the PV laboratory? ..... ☐ Yes ☐ No

Facility Physical Requirements for Location 1

Information regarding the physical requirements of the facility. If more than one area was declared, information is displayed for each.

Facility Physical Features

	Reference	Feature Area	
14.	8.3.2	Facilities are poliovirus dedicated laboratories, OR	☐
15.	8.3.2	Facilities are non-dedicated laboratories. Non-dedicated facilities must demonstrate effective segregation and decontamination procedures between work with poliovirus and other pathogens to prevent cross-contamination.	☐
16.	8.3.3	Containment perimeter is sealable for fumigation and with sealed penetrations to prevent uncontrolled outward airflow irrespective of the choice of primary containment.	☐
17.	NAC policy	Facility is equipped with a single door.	☐
18.	NAC policy	Facility is equipped with two doors between public areas and PV containment area.	☐
19.	8.3.5	Facility controls entry into the containment perimeter through a double-door personnel airlock.	☐
20.	8.3.5	Features include alarms, interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time.	☐
21.	8.3.5	Anterooms and airlocks are within the containment perimeter and sealable for fumigation.	☐
22.	8.3.6	Containment area marked with biohazard signs	☐
23.	8.3.8	Facility controls exit from containment perimeter with appropriate steps to prevent exposure to contaminated PPE or personnel (e.g., change area).	☐
24.	8.3.9	Exits are clearly marked.	☐
25.	8.3.15	Containment area equipped with vision panel(s) for visual monitoring of activities	☐
Feature Area Comments			☐

Primary Containment Devices

	Reference	Feature Area	
26.	8.3.4	Containment area equipped with Class II biosafety cabinet(s)	☐
27.	8.3.4	Containment area equipped with fully functional Class III biosafety cabinet(s) or similar isolators.	☐
28.	8.3.15	Containment area has closed systems that have been leak tested and validated (e.g., manufacturing processes and transfer of intermediates for use in vaccine production).	☐

Primary Containment Devices

	Reference	Feature Area	
29.	8.3.16	Containment area equipped with other primary containment devices (e.g., flexible film isolators, local exhaust ventilation)	☐

Feature Area Comments:

Decontamination Systems

	Reference	Feature Area	
30.	8.3.12	Containment area equipped with single door autoclave	☐
31.	8.3.12	Containment area equipped with a dedicated pass-through autoclave. Autoclave has the following features:	☐
31a.	8.3.12	• Bioseal	☐
31b.	8.3.12	• Interlocking doors to prevent opening the clean side prior to cycle completion	☐
31c.	8.3.12	• Sterilization of air discharge	☐
31d.	8.3.12	• Cycle recording mechanisms and alarms	☐
32.	8.3.12	Containment area equipped with a material airlock/decontamination chamber sealable for fumigation	☐
33.	8.3.12	Containment area equipped with a dunk tank containing sufficient active compound to inactivate poliovirus	☐
34.	NAC policy	Facility uses a tissue digester to dispose of PV animal waste (if applicable)	☐
35.	NAC policy	Facility uses an incinerator to dispose of biohazardous waste	☐

Feature Area Comments: ☐

HVAC Systems

	Reference	Feature Area	
36.	8.3.10	Controlled air system maintains inward directional airflow.	☐
36a.	NAC policy	• Visual monitoring device, which confirms directional airflow, provided at the laboratory entry	☐
37.	8.3.10	Ventilation system features:	☐
37a.	8.3.10	• Exhaust air is HEPA filtered	☐
37b.	8.3.10	• Dedicated exhaust for PV area	☐
37c.	8.3.10	• Dedicated supply for PV area	☐
37d.	8.3.10	• Shared supply for PV area with supply-side HEPA filters directly on containment perimeter	☐
37e.	8.3.10	• Backflow protection on supply air	☐

HVAC Systems

	Reference	Feature Area	
37f.	8.3.10	• Ductwork sealable for fumigation	☐
37g.	8.3.10	• Monitors/alarms to ensure directional airflow can be readily validated	☐
Feature Area Comments:			☐

Sinks and Showers

	Reference	Feature Area	
38.	NAC policy	Containment area equipped with a hand washing sink.	☐
39.	8.3.7	Containment area equipped with a hands-free or automated hand washing sink.	☐
40.	8.3.7	Sinks located within and near exit of containment perimeter.	☐
41.	8.3.8	Containment area equipped with a personnel exit shower.	☐
42.	8.3.8	Containment area equipped with a personnel walk-through exit shower.	☐
43.	8.3.8	Containment area equipped with an emergency shower.	☐
Feature Area Comments:			☐

Effluent Decontamination

	Reference	Feature Area	
44.	8.3.11	All effluents from within the containment perimeter are decontaminated with a validated inactivation procedure (e.g., EDS, chemical treatment of collected laboratory effluents)	☐
45.	8.3.11	Effluent decontamination includes handwash	☐
46.	8.3.11	Effluent decontamination includes shower/emergency shower water	☐
47.	8.3.11	Effluent decontamination includes eyewash	☐
48.	8.3.11	Effluent decontamination includes unsterilized autoclave condensate	☐
49.	8.3.11	Backflow prevention is implemented on all liquid services/utilities passing across the polio containment boundary and via measures to prevent release through traps, sinks and shower drains.	☐
50.	8.3.11	Effluent treatment system is dedicated to PV containment area	☐
51.	8.3.11	Non-dedicated effluent treatment system has appropriate measures for cross-contamination risk based on risk assessment	☐
52.	8.3.13	Kill-tank rooms or equivalent meet all construction, sealing, and HVAC requirements of the primary containment space	☐
53.	8.3.13	Kill-tank rooms or equivalent have an anteroom/personnel airlock for controlled entry	☐
54.	8.3.13	Kill-tank rooms have appropriate spill risk mitigation measures. Such mitigations include:	☐

Effluent Decontamination

	Reference	Feature Area	
54a.	8.3.13	• Berms	☐
54b.	8.3.13	• Leak detection systems or alarms	☐
54c.	8.3.13	• Sump pumps	☐

Feature Area Comments:

Security

	Reference	Feature Area	
55.	7.1.1	Security controls limit access to PV containment area to only authorized persons	☐
56.	7.3.1	Authorized persons are in compliance with personnel reliability policies	☐
57.	NAC policy	Entry door(s) to PV area has a magnetic lock or an UL approved lock and lock cylinder which are rated as burglary resistant	☐
58.	7.1.1	Locked door uses two-factor access control measure (e.g., card access system with personal access code)	☐
59.	NAC policy	Lock(s) fail secure and allow egress only	☐
60.	NAC policy	PV area(s) are enclosed by a permanent barrier from floor to ceiling, with entry doors that can be securely locked	☐
61.	NAC policy	Material used in the construction of the permanent barrier is of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent	☐
62.	NAC policy	Walls are permanent construction, floor to ceiling	☐
63.	7.1.1	Entries into PV containment area are recorded	☐
63a.	7.1.1	• Electronic records (e.g., proximity card system)	☐
63b.	7.1.1	• Paper records (e.g., sign in log)	☐
63c.	7.1.1	• Closed circuit television or video records	☐
63d.	7.1.1	• None	☐
64.	7.1.1	PV containment area equipped with video surveillance	☐
65.	7.1.1	PV containment area equipped with intrusion detection system	☐
66.	8.3.9	PV containment perimeter is equipped with emergency exit and/or other perimeter doors (not authorized for employee entrance)	☐
67.	8.3.9	Emergency exit doors from the containment perimeter are alarmed	☐
68.	NAC policy	External hardware is removed (or lock cores sealed) on all fire exits and other perimeter doors could provide access to the PV area	☐

Security

	Reference	Feature Area	
69.	8.3.9	PV containment perimeter is not equipped with emergency exit or other perimeter door(s) that could provide entrance into containment	☐

Feature Area Comments:

Storage Area

	Reference	Feature Area	
70.	10.5.3	PV material stored outside of the PV containment laboratory under appropriate containment conditions	☐
71.	10.5.2	PV material stored in dedicated freezer(s)	☐
72.	10.5.5	PV material storage area has recording and alarm systems to monitor freezers	☐
73.	10.5.5	PV material storage area equipped with a back-up emergency power source	☐

Feature Area Comments:

SECTION 3: PRINCIPAL INVESTIGATOR GENERAL WORK

Completed for each principal investigator using or storing PV infectious or potentially infectious materials. If work activities differ by poliovirus type (PV1, PV2, PV3), complete a separate Section 2 to report type-specific work.

PRINCIPAL INVESTIGATOR (PI): [PI_Name] **PI ID ###**

SECTION 3a: INFECTIOUS MATERIAL (IM)

1.Material type used or stored: .....

2. Material use schedule: (Daily, weekly, quarterly, annually, storage only) .....

3. Work activities include:

- ☐ Animal Work
- ☐ Antigen production
- ☐ Antiviral efficacy assays
- ☐ Antiviral resistance assays
- ☐ Other: _____
- ☐ None (Storage only)
- ☐ Immunology assays
- ☐ Inoculating specimens into PV permissive cells
- ☐ Nucleic acid detection or sequencing methods
- ☐ Nucleic acid extraction methods
- ☐ Not applicable
- ☐ Viral propagation
- ☐ Viral cloning
- ☐ Viral genetic modification
- ☐ Viral concentration/purification

4. Estimated routine range of PV working concentrations [infectious units/mL]:

☐ ≤10^3 ☐ 10^4-10^6 ☐ 10^7-10^9 ☐ >10^9 ☐ Unknown ☐ Not applicable for PIM

5. Estimated routine range of PV working volumes used:

☐ ≤10ml ☐ 11-100ml ☐ 101-500ml ☐ 501ml-1L ☐ 1-10L ☐ >10L ☐ None (Storage only)

6. Estimated maximum range of PV concentration used or stored [infectious units/ml]: .....

7. Materials are removed from the containment laboratory (for any reason) ..... ☐ Yes ☐ No

If yes, purpose for removal:

- ☐ Procedures performed in another location outside of containment perimeter
- ☐ Decontamination
- ☐ Transfer to another facility
- ☐ Other:

8. Materials inactivated for future work ..... ☐ Yes ☐ No

If yes, inactivation method(s) and parameters used:

Method	Parameters
☐ Extraction	
☐ Fixation	
☐ Heat	
☐ Irradiation	
☐ Other	

SECTION 3b: POTENTIALLY INFECTIOUS MATERIAL (PIM)

1. Material type used or stored: .....

2. Material use schedule: (Daily, weekly, quarterly, annually, storage only) .....

3. Work activities include:

- ☐ Animal Work
- ☐ Antigen production
- ☐ Antiviral efficacy assays
- ☐ Antiviral resistance assays
- ☐ Other:
- ☐ None (Storage only)
- ☐ Immunology assays
- ☐ Inoculating specimens into PV permissive cells
- ☐ Nucleic acid detection or sequencing methods
- ☐ Nucleic acid extraction methods
- ☐ Not applicable
- ☐ Viral propagation
- ☐ Viral cloning
- ☐ Viral genetic modification
- ☐ Viral concentration/purification

4. Estimated routine range of PV working concentrations [infectious units/mL]:

☐ ≤10^3 ☐ 10^4-10^6 ☐ 10^7-10^9 ☐ >10^9 ☐ Unknown ☐ Not applicable for PIM

5. Estimated routine range of PV working volumes used:

☐ ≤10ml ☐ 11-100ml ☐ 101-500ml ☐ 501ml-1L ☐ 1-10L ☐ >10L ☐ None (Storage only)

6. Estimated maximum range of PV concentration used or stored [infectious units/ml]: .....

7. Materials are removed from the containment laboratory (for any reason) ..... ☐ Yes ☐ No

If yes, purpose for removal:

- ☐ Procedures performed in another location outside of containment perimeter
- ☐ Decontamination
- ☐ Transfer to another facility
- ☐ Other:

8. Materials inactivated for future work ..... ☐ Yes ☐ No

If yes, inactivation method(s) and parameters used:

Method	Parameters
☐ Extraction	
☐ Fixation	
☐ Heat	
☐ Irradiation	
☐ Other	

SECTION 3c: PRINCIPAL INVESTIGATOR SPECIES SPECIFIC ANIMAL WORK

Information regarding animal species used in the PI's work plan. Please answer each question; if more than one animal species is used, provide information for each species. Complete section 3 for each poliovirus type if different type-specific (PV1, PV2, PV3) work activities are performed.

SPECIES: [SpeciesType]

1. PV type used or stored: .....

2. Estimated frequency of animal work: .....

3. Estimated routine range of animals used in a single experiment: .....

4. Containment device(s) used for manipulation of infected animals:

☐ Class II BSC ☐ Glove Box ☐ Inward Air Flow
☐ Class III BSC ☐ Downdraft Table ☐ Other:

5. Poliovirus infected animals housed in a separate room from other animals: ..... ☐ Yes ☐ No

6. Animal caging method(s) used:

☐ Conventional caging ☐ Ventilated containment caging system ☐ Conventional caging within inward flow ventilated enclosure

7. Personal protective equipment (PPE) worn in PV animal laboratory:

☐ Gloves ☐ Scrubs ☐ Eye/face protection ☐ Dedicated Lab Shoes
☐ Disposable wrap-around gown ☐ Safety Glasses ☐ Respirator ☐ PAPR
☐ Tyvek suit or coverall ☐ Face or surgical mask ☐ Shoe Covers
☐ Other:

SECTION 4: VALIDATION

I declare that the information given in this form has been review by me and is, to the best of my knowledge, complete and correct. I understand that any willful misrepresentation of fact would render _____[FacilityName] liable to disqualification from the GAP Containment Certification Scheme (CCS).

INSTITUTION REPRESENTATIVE

Printed name: _____

Signature: _____

Date: _____

BIOSAFETY OFFICER

Printed name: _____

Signature: _____

Date: _____

PRINCIPAL INVESTIGATOR

Printed name: _____

Signature: _____

Date: _____