



## 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.

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**Public reporting burden:** CDC estimates the average public reporting burden for this collection of information as 1.5 hours/minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Review Office; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).



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**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			
<input type="checkbox"/>	PV childhood immunization records	<input type="checkbox"/>	Medical clearance for respirator
<input type="checkbox"/>	Adult IPV booster	<input type="checkbox"/>	Respirator fit test
<input type="checkbox"/>	PV proof of immunity	<input type="checkbox"/>	Tuberculosis skin test
<input type="checkbox"/>	Other required immunizations:		
<input type="checkbox"/>	Other:		



B. Visitors			
<input type="checkbox"/>	PV childhood immunization records	<input type="checkbox"/>	Medical clearance for respirator
<input type="checkbox"/>	Adult IPV booster	<input type="checkbox"/>	Respirator fit test
<input type="checkbox"/>	PV proof of immunity	<input type="checkbox"/>	Tuberculosis skin test
<input type="checkbox"/>	Other required immunizations:		
<input type="checkbox"/>	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					
<input type="checkbox"/>	Planning	<input type="checkbox"/>	Equipment	<input type="checkbox"/>	Shipping
<input type="checkbox"/>	Purchasing	<input type="checkbox"/>	Testing	<input type="checkbox"/>	Decontamination
<input type="checkbox"/>	Personnel	<input type="checkbox"/>	Quality Assurance/Quality Control	<input type="checkbox"/>	Management Review
<input type="checkbox"/>	Facilities	<input type="checkbox"/>	Inventory		
<input type="checkbox"/>	Other:				

B. Support processes					
<input type="checkbox"/>	Quality Management System (QMS)	<input type="checkbox"/>	Occupational Health	<input type="checkbox"/>	Maintenance
<input type="checkbox"/>	Environmental Health and Safety	<input type="checkbox"/>	Security	<input type="checkbox"/>	Contractors/Supplies
<input type="checkbox"/>	Training	<input type="checkbox"/>	Emergency Response		
<input type="checkbox"/>	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:

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





- 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**

	<b>Reference</b>	<b>Feature Area</b>	
14.	8.3.2	Facilities are poliovirus dedicated laboratories, OR	<input type="checkbox"/>
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.	<input type="checkbox"/>
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.	<input type="checkbox"/>
17.	NAC policy	Facility is equipped with a single door.	<input type="checkbox"/>
18.	NAC policy	Facility is equipped with two doors between public areas and PV containment area.	<input type="checkbox"/>
19.	8.3.5	Facility controls entry into the containment perimeter through a double-door personnel airlock.	<input type="checkbox"/>
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.	<input type="checkbox"/>
21.	8.3.5	Anterooms and airlocks are within the containment perimeter and sealable for fumigation.	<input type="checkbox"/>
22.	8.3.6	Containment area marked with biohazard signs	<input type="checkbox"/>
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).	<input type="checkbox"/>
24.	8.3.9	Exits are clearly marked.	<input type="checkbox"/>
25.	8.3.15	Containment area equipped with vision panel(s) for visual monitoring of activities	<input type="checkbox"/>
		Feature Area Comments	<input type="checkbox"/>

**Primary Containment Devices**

	<b>Reference</b>	<b>Feature Area</b>	
26.	8.3.4	Containment area equipped with Class II biosafety cabinet(s)	<input type="checkbox"/>
27.	8.3.4	Containment area equipped with fully functional Class III biosafety cabinet(s) or similar isolators.	<input type="checkbox"/>
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).	<input type="checkbox"/>



**Primary Containment Devices**

	<b>Reference</b>	<b>Feature Area</b>	
29.	8.3.16	Containment area equipped with other primary containment devices (e.g., flexible film isolators, local exhaust ventilation)	<input type="checkbox"/>

Feature Area Comments:

**Decontamination Systems**

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

Feature Area Comments:

**HVAC Systems**

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

**HVAC Systems**

	Reference	Feature Area	
37f.	8.3.10	• Ductwork sealable for fumigation	<input type="checkbox"/>
37g.	8.3.10	• Monitors/alarms to ensure directional airflow can be readily validated	<input type="checkbox"/>

Feature Area Comments:

**Sinks and Showers**

	Reference	Feature Area	
38.	NAC policy	Containment area equipped with a hand washing sink.	<input type="checkbox"/>
39.	8.3.7	Containment area equipped with a hands-free or automated hand washing sink.	<input type="checkbox"/>
40.	8.3.7	Sinks located within and near exit of containment perimeter.	<input type="checkbox"/>
41.	8.3.8	Containment area equipped with a personnel exit shower.	<input type="checkbox"/>
42.	8.3.8	Containment area equipped with a personnel walk-through exit shower.	<input type="checkbox"/>
43.	8.3.8	Containment area equipped with an emergency shower.	<input type="checkbox"/>

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)	<input type="checkbox"/>
45.	8.3.11	Effluent decontamination includes handwash	<input type="checkbox"/>
46.	8.3.11	Effluent decontamination includes shower/emergency shower water	<input type="checkbox"/>
47.	8.3.11	Effluent decontamination includes eyewash	<input type="checkbox"/>
48.	8.3.11	Effluent decontamination includes unsterilized autoclave condensate	<input type="checkbox"/>
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.	<input type="checkbox"/>
50.	8.3.11	Effluent treatment system is dedicated to PV containment area	<input type="checkbox"/>
51.	8.3.11	Non-dedicated effluent treatment system has appropriate measures for cross-contamination risk based on risk assessment	<input type="checkbox"/>
52.	8.3.13	Kill-tank rooms or equivalent meet all construction, sealing, and HVAC requirements of the primary containment space	<input type="checkbox"/>
53.	8.3.13	Kill-tank rooms or equivalent have an anteroom/personnel airlock for controlled entry	<input type="checkbox"/>
54.	8.3.13	Kill-tank rooms have appropriate spill risk mitigation measures. Such mitigations include:	<input type="checkbox"/>

## Effluent Decontamination

	Reference	Feature Area	
54a.	8.3.13	• Berms	<input type="checkbox"/>
54b.	8.3.13	• Leak detection systems or alarms	
54c.	8.3.13	• Sump pumps	<input type="checkbox"/>

Feature Area Comments:

## Security

	Reference	Feature Area	
55.	7.1.1	Security controls limit access to PV containment area to only authorized persons	<input type="checkbox"/>
56.	7.3.1	Authorized persons are in compliance with personnel reliability policies	<input type="checkbox"/>
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	<input type="checkbox"/>
58.	7.1.1	Locked door uses two-factor access control measure (e.g., card access system with personal access code)	<input type="checkbox"/>
59.	NAC policy	Lock(s) fail secure and allow egress only	<input type="checkbox"/>
60.	NAC policy	PV area(s) are enclosed by a permanent barrier from floor to ceiling, with entry doors that can be securely locked	<input type="checkbox"/>
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	<input type="checkbox"/>
62.	NAC policy	Walls are permanent construction, floor to ceiling	<input type="checkbox"/>
63.	7.1.1	Entries into PV containment area are recorded	<input type="checkbox"/>
63a.	7.1.1	• Electronic records (e.g., proximity card system)	<input type="checkbox"/>
63b.	7.1.1	• Paper records (e.g., sign in log)	<input type="checkbox"/>
63c.	7.1.1	• Closed circuit television or video records	<input type="checkbox"/>
63d.	7.1.1	• None	<input type="checkbox"/>
64.	7.1.1	PV containment area equipped with video surveillance	<input type="checkbox"/>
65.	7.1.1	PV containment area equipped with intrusion detection system	<input type="checkbox"/>
66.	8.3.9	PV containment perimeter is equipped with emergency exit and/or other perimeter doors (not authorized for employee entrance)	<input type="checkbox"/>
67.	8.3.9	Emergency exit doors from the containment perimeter are alarmed	<input type="checkbox"/>
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	<input type="checkbox"/>



**Security**

	<b>Reference</b>	<b>Feature Area</b>	
69.	8.3.9	PV containment perimeter is not equipped with emergency exit or other perimeter door(s) that could provide entrance into containment	<input type="checkbox"/>

Feature Area Comments:

**Storage Area**

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

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.

<b>PRINCIPAL INVESTIGATOR (PI): [PI_Name]</b>	<b>PI ID ###</b>
<b>SECTION 3a: INFECTIOUS MATERIAL (IM)</b>	

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

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

3. Work activities include:
- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Animal Work                 | <input type="checkbox"/> Immunology assays                              | <input type="checkbox"/> Viral propagation                |
| <input type="checkbox"/> Antigen production          | <input type="checkbox"/> Inoculating specimens into PV permissive cells | <input type="checkbox"/> Viral cloning                    |
| <input type="checkbox"/> Antiviral efficacy assays   | <input type="checkbox"/> Nucleic acid detection or sequencing methods   | <input type="checkbox"/> Viral genetic modification       |
| <input type="checkbox"/> Antiviral resistance assays | <input type="checkbox"/> Nucleic acid extraction methods                | <input type="checkbox"/> Viral concentration/purification |
| <input type="checkbox"/> Other: _____                |   |   |
| <input type="checkbox"/> None (Storage only)         | <input type="checkbox"/> Not applicable                                 |   |

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

≤10<sup>3</sup>     10<sup>4</sup>-10<sup>6</sup>     10<sup>7</sup>-10<sup>9</sup>     >10<sup>9</sup>     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
<input type="checkbox"/> Extraction	
<input type="checkbox"/> Fixation	
<input type="checkbox"/> Heat	
<input type="checkbox"/> Irradiation	
<input type="checkbox"/> 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
- Immunology assays
- Viral propagation
- Antigen production
- Inoculating specimens into PV permissive cells
- Viral cloning
- Antiviral efficacy assays
- Nucleic acid detection or sequencing methods
- Viral genetic modification
- Antiviral resistance assays
- Nucleic acid extraction methods
- Viral concentration/purification
- Other:
- None (Storage only)
- Not applicable

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

- $\leq 10^3$
- $10^4-10^6$
- $10^7-10^9$
- $>10^9$
- Unknown
- Not applicable for PIM

5. Estimated routine range of PV working volumes used:

- $\leq 10\text{ml}$
- 11-100ml
- 101-500ml
- 501ml-1L
- 1-10L
- $>10\text{L}$
- 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
<input type="checkbox"/> Extraction	
<input type="checkbox"/> Fixation	
<input type="checkbox"/> Heat	
<input type="checkbox"/> Irradiation	
<input type="checkbox"/> 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:

