

APPLICATION FORM INTERIM CERTIFICATE OF CONTAINMENT (ICC)

PLEASE PROVIDE ALL RESPONSES AND DOCUMENTS IN ENGLISH LANGUAGE

A. PART TO BE COMPLETED BY THE DESIGNATED POLIOVIRUS-ESSENTIAL FACILITY ⁽¹⁾

I. PEF Organization Information

Assigned PEF Identification: ⁽²⁾

<p>Full Name of the organization:</p> <p>Name of the head of the organization:</p>	<p>Full address/location (as it should appear on the postal address):</p> <p>E-mail :</p> <p>Telephone :</p>
<p>Contact person for all correspondence related to this application:</p> <p>Full Name:</p> <p>Position:</p>	<p>Correspondence address: (as it should appear on the postal address):</p> <p>E-mail :</p> <p>Telephone :</p>
<p>Type of Organization (Check all that are relevant to this application):</p> <p><input type="checkbox"/> Vaccine manufacture</p> <p><input type="checkbox"/> Laboratory (including QC)</p> <p><input type="checkbox"/> Repository ONLY (NO handling/manipulation of retained material)</p> <p><input type="checkbox"/> Other (Please specify):</p>	<p>Type(s) of work Conducted (Check all that are relevant to this application):</p> <p><input type="checkbox"/> Vaccine production</p> <p><input type="checkbox"/> Testing (QC)</p> <p><input type="checkbox"/> Diagnostic</p> <p><input type="checkbox"/> Research and development</p> <p><input type="checkbox"/> Animal related</p> <p><input type="checkbox"/> Other (Please specify):</p>

II. Type of Application

Application date (DD-MM-YYYY):	
Application for:	
<input type="checkbox"/>	Interim Certificate of Containment
<input type="checkbox"/>	First application for extension of ICC validity
<input type="checkbox"/>	Second application for extension of ICC validity

III. Type of Infectious Poliovirus material retained by the organization and volumes per type ⁽³⁾⁽⁴⁾

	Material	Quantity (metric units) provide range (in foot add ranges as per CP model)
<input type="checkbox"/>	WPV1	
<input type="checkbox"/>	WPV2	
<input type="checkbox"/>	WPV3	
<input type="checkbox"/>	VDPV1	
<input type="checkbox"/>	VDPV2	
<input type="checkbox"/>	VDPV3	
<input type="checkbox"/>	Sabin1	
<input type="checkbox"/>	Sabin2	
<input type="checkbox"/>	Sabin3	
<input type="checkbox"/>	Monovalent OPV1	
<input type="checkbox"/>	Monovalent OPV2	
<input type="checkbox"/>	Monovalent OPV3	
<input type="checkbox"/>	Bivalent OPV (1 & 3)	
<input type="checkbox"/>	Trivalent OPV (1, 2 & 3)	
<input type="checkbox"/>	NOPV2	
<input type="checkbox"/>	Other/new poliovirus strains, (e.g. S19)	
<input type="checkbox"/>	Other, please specify: ⁽³⁾	

IV. PEF Staffing Information ⁽⁵⁾

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V. Part A Declaration

On behalf of the organization, I declare that the information given in this form is, to the best of our knowledge, complete and correct. We understand that any willful mis-statement would render us liable to disqualification from the containment certification process.

Acknowledged by:	Signature witnessed by:
Name :	Name :
Organization/Position :	Organization/Position :
Date (DD-MM-YYYY) :	Date (DD-MM-YYYY) :

B. PART TO BE FILLED BY THE NATIONAL AUTHORITY FOR CONTAINMENT (NAC)

I. NAC information

NAC details	<p>Country :</p> <p>Organization / Department / Unit:</p> <p>Full address: (as it should appear on the postal address):</p> <p>E-mail :</p> <p>Telephone :</p>
NAC Request	<p><input type="checkbox"/> Interim Containment Certificate</p> <p><input type="checkbox"/> ICC Application Extension</p>
Supporting documents for submission to GCC	
Supplied by the PEF	<input type="checkbox"/> Completed Application – Part A
Supplied by the NAC ⁽⁵⁾	<p><input type="checkbox"/> Audit Plan ⁽⁶⁾</p> <p><input type="checkbox"/> Qualification of Auditors or NAC Certification ⁽⁷⁾</p> <p><input type="checkbox"/> Audit Report</p> <p><input type="checkbox"/> Audit Findings and Corrective Action Plan</p> <p><input type="checkbox"/> Secondary Safeguards ⁽⁸⁾</p> <p><input type="checkbox"/> Tertiary Safeguards ⁽⁹⁾</p> <p><input type="checkbox"/> Additional Documents (clarify) ⁽¹⁰⁾</p>

II. Part B Declaration

I declare that the information given in this form is to the best of our knowledge, complete and correct.

Acknowledged by:	Signature witnessed by:
Name :	Name :
Organization/Position :	Organization/Position :
Date (DD-MM-YYYY) :	Date (DD-MM-YYYY) :

C. PART TO BE FILLED BY THE GLOBAL CERTIFICATION COMMISSION (GCC)

I. GCC Information

Name:	Position:	Email:
		Telephone:
Date processed (DD-MM-YYYY) :		
Supporting documents received by GCC include		
Supplied by the PEF	<input type="checkbox"/>	Completed Application – Part A
Supplied by the NAC	<input type="checkbox"/>	Completed Application – Part B
	<input type="checkbox"/>	Audit Plan
	<input type="checkbox"/>	Qualification of Auditors or NAC Certification
	<input type="checkbox"/>	Audit Report
	<input type="checkbox"/>	Audit Findings and Corrective Action Plan
	<input type="checkbox"/>	Secondary Safeguards
	<input type="checkbox"/>	Tertiary Safeguards
	<input type="checkbox"/>	Additional Documentation
GCC Review Results	<input type="checkbox"/>	Approved for ICC
	<input type="checkbox"/>	ICC First extension Approved
	<input type="checkbox"/>	ICC Second extension Approved
Date of GCC review completion (DD-MM-YYYY) :		
Comments:		

II. Acknowledgement

Acknowledged by:	
Name	:
Organization/Position	:
Date (DD-MM-YYYY)	:

Application Instructions

- (1) This application is for a Polio Essential Facility (PEF) located at the address of the primary facility. A PEF may have several locations within a metropolitan such as a manufacturing organizations with several campuses. PEFs that are part of a different organization or PEFs located in other parts of the country, even if under a central management, must submit a separate application for each PEF.
- (2) The PEF identification number is the number that was assigned to the PEF at the time a Certificate of Participation (CP) was awarded.
- (3) List all poliovirus and poliovirus materials as defined by WHO-GAP
- (4) Diagnostic PEFs only need to list volumes of materials stored for quality control purposes (and/or post control), that are stored for potential use in the future, or are historical collections.
- (5) The number and types (technicians, researchers, supervisors, managers, support, etc.) that are involved with the poliovirus work.
- (6) The Audit Plan sample can be used as framework for the NAC may submit their own description of the audit process that includes the policies and practices that were audited, the auditors and technical support involved in the audit and information on who was interviewed.
- (7) The listed documents should be attached to the application and submitted as one package. The information should be provided on the standard template forms.
- (8) The audit application documentation may be submitted prior to conducting audits. If the box is checked it indicates the documents are attached or have been submitted previously.
- (9) Refer to GAP for requirement.
- (10) Refer to GAP for requirement.
- (11) Attach a list of all additional documentation that have been submitted with this application.