Note: This form is provided in MS Word .docx format for easier use. Space provided, if insufficient, may be expanded or additional sheets may be added, as needed. Please do not change or alter the questions or clarification requested.

APPLICATION FORM

certificate of containment (CC)

please provide all responses and documents in english

1. PART TO BE COMPLETED BY THE POLIOVIRUS-ESSENTIAL FACILITY (1)
2. PEF Organization Information

|  |  |  |  |
| --- | --- | --- | --- |
| Facility CCS intention: (please select one) | | | |
|  | Application for Certificate of Containment (CC) directly from a Certificate of Participation (CP) | CP code (2): |  |
|  | Application for CC as upgrade from an Interim Certificate of Containment (ICC) | CP code (2): |  |
| ICC code (2): |  |

|  |  |
| --- | --- |
| Full name of the organization:    Name of the head of the organization: | Complete address:  (as it should appear on the postal address):        E-mail :  Telephone : |
| Focal person(s) at the instituion should there be a need for correspondence related to this application:  Full name:    Position: | Correspondence address:  (as it should appear on the postal address):          E-mail :  Telephone : |
| Type of organization  (Check all that are relevant to this application):  Vaccine manufacture  Laboratory (including QC)  Repository ONLY (NO handling/manipulation of retained material)  Other (Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | Type(s) of work conducted  (Check all that are relevant to this application):  Vaccine production  Testing (QC)  Diagnostic  Research and development  Animal related  Other (Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |

1. Type of application

|  |  |
| --- | --- |
| Application date (DD-MM-YYYY): | |
| Application for: (please select one) | |
|  | Certificate of Containment – initial application |
|  | Certificate of Containment – re-certification application |

1. Type of infectious poliovirus material retained and volume per type (3)(4)

|  |  |  |
| --- | --- | --- |
|  | Poliovirus Type and Serotype | Quantity (metric units) provide range (in feet add ranges as per CP model) |
|  | WPV1 |  |
|  | WPV2 |  |
|  | WPV3 |  |
|  | VDPV1 |  |
|  | VDPV2 |  |
|  | VDPV3 |  |
|  | Sabin1 |  |
|  | Sabin2 |  |
|  | Sabin3 |  |
|  | Sabin Monovalent OPV1 |  |
|  | Sabin Monovalent OPV2 |  |
|  | Sabin Monovalent OPV3 |  |
|  | Sabin Bivalent OPV (1 & 3) |  |
|  | Sabin Trivalent OPV (1, 2 & 3) |  |
|  | novel monovalent OPV1 (nOPV1) |  |
|  | novel monovalent OPV2 (nOPV2) |  |
|  | novel monovalent OPV3 (nOPV3) |  |
|  | Other formulation of novel monovalent OPV:  Please specficy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  Please specficy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |  |
|  | Novel poliovirus strains such as but not limited to S19-poliovirus strains (please specifiy type), nOPV, PVSRIPO, CAVA, etc. |  |
|  | Other, please specify: |  |

1. Rationale for the retention of poliovirus materials post-eradication

|  |
| --- |
| Please describe: (please add additional sheet, as needed) |

1. PEF staffing information (5)

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|  |

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.

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| --- | --- |
| Acknowledged by: | Witnessed by: |
| Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organization/Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organization/Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. PART TO BE FILLED BY THE NATIONAL AUTHORITY FOR CONTAINMENT (NAC)
2. NAC information

|  |  |
| --- | --- |
| NAC details | Country:  Organization / Department / Unit:  Full address:      E-mail:  Telephone: |

|  |  |
| --- | --- |
| Submission for: (please select one) | Certificate of Containment – initial application |
| Certificate of Containment – re-certification application |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Only to be filled in for initial applications for certificate of containment (please select one) | | | | | | | | | |
|  | Application for CC directly from CP | CP code (2): |  | | CP end-validity date: (DD-MM-YYYY) | | |  | |
|  | Application for CC as upgrade from an ICC | CP code (2): |  | | | | | | |
| ICC code (2): |  | | ICC end-validity date: (DD-MM-YYYY) | | |  | |
| Standard against which ICC was issued: | |  | | GAPIII |  | | GAPIV |
| GAPIII: WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2015  GAPIV: WHO Global Action Plan for Poliovirus Containment, 4th edition, 2020 | | | | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sections that follow are to be filled-in for initial- and recertification CC applications: | | | | |
| Scale of audit performed: |  | Full-scope audit |  | Reduced-scope audit |
|  | Other: (please describe) | | |
| Audit timing coincided with: |  | ICC Year 1 Periodic Audit |  | ICC Year 2 Periodic Audit |
|  | End-validity of ICC |  | End-validity of CP |
|  | Other: (please describe) | | |
| Audit against GAPIV: |  | Yes |  | No |
| If No, please indicate standard used and reasons for using the said standard: | | | |

|  |  |
| --- | --- |
| Supporting documents for submission to GCC | |
| Supplied by the PEF | Completed Application – Part A |
| Additional Documents (clarify) |
| Supplied by the NAC | Audit Plan (6) |
| Qualification of Auditors or NAC Certification including indication of GAPIV training (6) |
| Audit Report |
| Audit Findings and Corrective Action Plan |
| Follow-up reports on previous ICC Audit Findings and Corrective Action Plan |
| Evidence or reports indicating effective closure of identified nonconformities (NC) (new and previous ICC audit NCs) |
| Evidence of Immunization Coverage Safeguards (7) |
| Evidence of Environmental Safeguards (7) |
| Additional Documents (clarify) (8) |

|  |
| --- |
| Please use this section to provide any other relevant information to the GCC in support of this CC appplication submission: |

In the interest of ensuring NAC data is up-to-date within the WHO database, please complete the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Generic e-mail ID of the NAC: | |  | | |
| No | Name (Title SURNAME, First Name, Middle Name etc.) | Designation  in the NAC | Institutional Designation | Phone number \_\_\_\_\_\_  E-mail ID \_\_\_\_\_\_\_\_\_\_ |
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|  |  |  |  |  |
|  | Please add rows as needed |  |  |  |
| Please indicate the e-mail ID(s) that should be included in all correspondence to the NAC: | |  | | |

Part B Declaration

On behalf of the NAC, 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organization/Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Organization/Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

C. PART TO BE FILLED BY THE GLOBAL COMMISSION FOR THE CERTIFICATION OF THE ERADICATION OF POLIOMYELITIS (GCC)

1. GCC Information

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Position: | | Email: |
| Date processed (DD-MM-YYYY) : | | | |
| Supporting documents received by GCC: | | | |
| Supplied by the PEF |  | Completed Application – Part A | |
|  | Additional Documentation | |
| Supplied by the NAC |  | Completed Application – Part B | |
|  | Audit Plan | |
|  | Qualification of Auditors or NAC Certification | |
|  | Audit Report | |
|  | Audit Findings and Corrective Action Plan | |
|  | Follow-up reports on previous ICC Audit Findings and Corrective Action Plan | |
|  | Evidence or reports indicating effective closure of identified nonconformities (NC) (new and previous ICC audit NCs) | |
|  | Evidence Immunization Coverage Safeguards | |
|  | Evidence Environmental Safeguards | |
|  | Additional Documentation | |
| Type of CC application |  | Initial application | |
|  | Recertification application | |
| GCC Review Results |  | Approved | |
|  | Not approved | |
| Date of GCC review completion (DD-MM-YYYY) : | | | |

|  |
| --- |
| Comments: |

1. Acknowledgement

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

Instructions**:**

1. This application is for a poliovirus-essential facility (PEF) located at the address of the primary or main facility. A PEF may have several sites within a metropolitan area such as a vaccine manufacturing organizations with several campuses. PEFs that are part of a different organizations or PEFs located in other parts of the country, even when under the same institutitional management, must submit a separate application for each PEF. This application is for the use of poliovirus-essential facilities that hold a valid certificate of participation (CP) or an interim certificate of containment (ICC).
2. The CP or ICC code is the unique identifier assigned to the facility and has the following format: (ISO3-letter country code) - type of CCS certificate i.e., CP or ICC – date of application submission in ISO format YYYYMMDD – 3-digit unique number.
3. List all poliovirus materials defined in GAPIV
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 of staff (technicians, researchers, supervirsors, managers, support, etc.) that are involved with poliovirus work.
6. The Audit Plan (known as the ICC plan) sample can be used as framework for the NAC to submit a description of the national audit process which may include timelines for auditing activities involving the requirements in the elements and subelements of GAPIV, the audit team (lead auditor, audits, technical experts, etc.), information on who those interviewed and any other relevant information. The listed documents should be attached to the application and submitted as single package. The information should be provided on the standard template forms. The audit audit plan may be submitted prior to conducting audits. If the box is checked it indicates the documents are attached or have been submitted previously.
7. Refer to GAPIV for requirement.
8. Attach a list of all additional documentation that have been submitted with this application.