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.

Poliovirus containment certification scheme

containment audit PROPOSAL

please provide all responses and documents in english

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| A Containment Audit Proposal is to be submitted to the GCC – CWG for endorsement prior to the initiation of any audit activity associated with a facility interim certificate of containment (ICC) or certificate of containment (CC) application as described in the Poliovirus Containment Certification Scheme, second edition (CCS 2.0). The Containment Audit Plan for an ICC or CC application is to be developed by the National Authority of Containment (NAC) by completing this form and attaching the relevant documentation. This plan is to be developed for the audit activities for each facility in the country intending to progress within or to a subsequent containment certification phase e.g., CP to ICC, ICC to CC or CP to CC. It consists of two major sections: (1) timelines of audit activities and (2) auditors and the audit team performing the audit activities. If feasible, the initial submission of a Containment Audit Plan for an ICC or CC should include timelines for initial and annual periodic audits, recertification audits or audits performed under special circumstances e.g., use of an ICC annual periodic audit to perform an audit for an upgrade from an ICC to a CC application. The completed Containment Audit Plan with the necessary supporting documentation can be submitted at any time to the GCC – CWG for review and endorsement at their monthly virtual meetings. Submissions should be made through the GCC-CWG Secretariat via e-mail at: containment@who.intFacility ICC or CC applications submitted without a prior endorsement of a Containment Audit Plan may impede the ability of the GCC – CWG to ensure a harmonized approach to the review of audits from different countries, leading to challenges endorsing subsequent certificate applications. |

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| National authority for containment (NAC) information relevant to this Containment Audit Plan submission: |
| NAC Name and Country:  |  | Name, designation and e-mail ID of NAC focal person in case of correspondence related to this submission:  |  |
| Full name of the facility for which this Containment Audit Plan is submitted: |
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| Type of organization (facility) (Check all that apply) | Type(s) of work conducted (Check all that apply) |
| [ ]  | Vaccine manufacturer | [ ]  | Vaccine production |
| [ ]  | Laboratory (including QC) | [ ]  | Testing (QC) |
| [ ]  | Storage-only (no handling) | [ ]  | Diagnostic |
| [ ]  | Other (Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | [ ]  | Research and development |
| [ ]  | Animal related |
| [ ]  | Other (Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |

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| Containment Audit Plan for: (please check all that apply) |
| Interim Certificate of Containment (ICC)  | Certificate of Containment (CC) |
| [ ]  | Initial audit | [ ]  | Audit relevant to upgrade from an ICC |
| [ ]  | ICC Year 1 periodic audit | [ ]  | Initial audit |
| [ ]  | ICC Year 2 periodic audit | [ ]  | CC Year 1 periodic audit |
| [ ]  | Others (e.g. facility redesign, verification of closure of NC1s): please specify | [ ]  | CC Year 2 periodic audit |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | Re-certification audit |
| [ ]  | Others: please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Scale of the audit to be performed:  | [ ]  | Full-scope audit | [ ]  | Reduced-scope audit |
| [ ]  | Others: (please describe) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Duration of document review: | From: | To: |
| Duration of on-site audit to be performed: | From: | To: |
| Justification for audit duration (i.e. how the duration of the audit was determined): |

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| Timelines for the Implementation of CCS Audit Planning Activities, Audit Activities and Post-Audit Activities |
| Table 1: Timelines for Audit Planning Activities, Audit Activities and Post-Audit ActivitiesPlease add or delete rows as needed to delineate activities of the different stages of the CCS process e.g., ICC Initiation and Planning; ICC Initial audit, reporting and follow-up; ICC Review and approval; ICC Monitoring and Renewal; CC Reporting, Review and Approval; CC Monitoring and CC Renewal. Before filling in this table, review Annex 1 for a table of audit activities to be included and additional instructions. |
| Activity | Timelines (please use: Month Year e.g., October 2024 orfrom Month Year to Month Year e.g., December 2024 to January 2025) | Comments |
| Interim Certificate of Containment (ICC) Application\* |
| Stage e.g., Initiation and Planning  |
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| Stage e.g., Initial audit, reporting and follow-up, etc. |
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| Stage e.g., Review and approval |
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| Stage e.g., Monitoring and Renewal |
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| Certificate of Containment (CC) Application  |
| Stage e.g., Reporting, Review and Approval |
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| Stage e.g., Monitoring |
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| Stage e.g., Renewal |
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\*the activities grouped by stages under the ICC application also apply to facilities moving directly to a CC from a CP.

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| Auditors and Audit Team  |

When completing this section, the NAC should aim to demonstrate that individual auditors meet the requirements as described in the CCS (Table 2). The GCC – CWG may also consider the competency of the team as a whole. For auditors not yet endorsed by the GCC – CWG, an Audit Team Member Application Form should be completed by the candidate auditor and submitted to the NAC for approval and to the GCC – CWG for endorsement. The Audit Team Member Application Form should also be completed by all other audit team members e.g., technical experts, translator and observers for submission to the NAC and the GCC – CWG for endorsement. It is recommended that the submission of the Audit Team Member Application Forms be done on an ad hoc basis to the GCC – CWG by e-mail at: containment@who.int .

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| Table 2: Audit team members assigned to perform the audit-relevant activities for the facility mentioned\* |
| No | First name and LAST NAME | Institution and Institutional Designation | Role in Audit Team\* | Has received endorsement fromGCC – CWG(Yes/No/Pending) | Participation in GAPIII and GAPIV Training  |
| 1 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 2 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 3 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 4 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 5 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 6 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| 7 |  |  |  | [ ]  | Yes | [ ]  | No | [ ]  | Pending | [ ]  | GAPIII | [ ]  | GAPIV | [ ]  | GAPIV (scheduled) |
| Please add additional rows as needed.\*Please list all audit team members including team lead, lead auditor, auditor, technical experts, translators, observers (auditor-in-training) |

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| Table 3: Competency and expertise of the audit team as a wholeNote: This table should be modified as needed to demonstrate that the audit team as a whole has the appropriate competencies, experience and expertise needed to perform the audit. Please indicate the role of each audit team member including name and check the relevant boxes applicable to the members competency, experience and expertise in the disciplines relevant to the biorisk management elements in GAPIV.  |
| Expertise and experience of audit team members in auditing different facility-types and disciplines of GAPIVbiorisk management elements\* | Member 1&Team LeadFirst name and LAST NAME | Member 2&Lead AuditorFirst name and LAST NAME | Member 3&AuditorFirst name and LAST NAME | Member 4&AuditorFirst name and LAST NAME | Member 5&Technical ExpertFirst name and LAST NAME | Member 6&Technical ExpertFirst name and LAST NAME | Member 7&TranslatorFirst name and LAST NAME | Member 8&Auditor-in-TrainingFirst name and LAST NAME |
| Biorisk management | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Biosecurity  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Good microbiological practice and procedure  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Quality management system | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Safety management systems | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Good manufacturing practices  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Vaccine manufacturing and production environments | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Laboratory environments e.g., diagnostics, research, etc.  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Vaccine quality control  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Storage and repositories  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Animal facilities  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Planning and design of containment facilities  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Containment engineering principles and concepts | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Emergency preparedness and response | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Security | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Infectious waste management  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Transport of infectious goods | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
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| Add additional rows as needed  |

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| Please use this section to provide any other relevant information to the GCC in support of this Containment Audit Plan (i.e. use of international resources):  |

NAC ACKNOWLEDGEMENT

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

GCC – CWG Review Outcome

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| Date processed (DD-MM-YYYY) :       |
| Documentation supplied by the NAC in regards to this submission: | [ ]  | Complete | [ ]  | Incomplete |
| Indicate additional documentation needed:  |  |
| Date reviewed (DD-MM-YYYY) : |
| Outcome of review by GCC – CWG:  | [ ]  | Endorse | [ ]  | Not endorsed  |
| Comments:  |
|  |

GCC – CWG ENDORSEMENT

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

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| Annex 1 |

Instructions for completing Table 1:

* Table 4 (next page) should be used to provide the timelines for the relevant CCS audit planning activities, audit activities and post-audit activities implemented at the national level for the facility mentioned. This template consists of three columns:
	1. Activity: List all relevant CCS audit planning, audit and post-audit activities that will be undertaken for the facility mentioned. As a reference, a summary providing a broad overview of the different CCS audit-relevant activities (please see also Chapters 2 and 4 of the CCS) is shown (Table 1). The activities indicated in Table 1 may be adjusted as needed, additional activities added or those indicated dropped to reflect the implementation of the CCS at the country level. Activities listed are expected to meet the guidelines laid out in the CCS.
	2. Timelines: Timelines for the implementation of the different CCS audit-relevant activities should be indicated using the following format: Month Year e.g., October 2024 or from Month Year to Month Year e.g., December 2024 to January 2025.
	3. Comments: Brief rationale or justification in situations where CCS audit-relevant activities are dropped, changed or added.
* In the development of these timelines, NACs should take into consideration the following:
	1. Alignment with the previously submitted facility time-bound action plan to achieve an ICC or CC submitted as part of the previously awarded CP.
	2. Timelines to achieve the containment requirements for the certification of WPV eradication by end-2026 as per GCC recommendation[[1]](#footnote-1)
* Any additional information may be included in the comments column or annexed with this submission.

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| Table 4: CCS Audit Planning Activities, Audit Activities and Post-Audit Activities summarized from the CCS (see Chapters 2 and 4 of the CCS) |
| Interim Containment Certification (ICC))\* | Stage | Activities |
| 1. Initiation and Planning
 | * Formal engagement of facility in the CCS process through a contract or another appropriate modality with the NAC
* NAC plans initial full-scope ICC audit with PEF including:
	+ Initial visit or gap assessment, if any
	+ Determination of audit duration; number, assignment and roles and responsibilities of GCC – CWG- endorsed auditors based on facility-type, number of sites, scale of processes, etc.
	+ Development of audit plan, list of key facility personnel for interview, list of documents for off-site review (see Document Request Form), facility regulations to be considered by the audit team (e.g. vaccination, identification) etc. This is followed by:
		- Sharing with audit team members for agreement, clarification and discussion, as needed
		- Agreement reached by NAC, lead auditor/audit team and facility
		- Final version shared with facility (at least 20 working days before audit)
* NAC shares relevant documentation with lead auditor/audit team e.g., evidence of immunization coverage and environmental safeguards described in GAPIV; facility ICC application form; GCC-countersigned CP, etc.
* Facility submits documents requested by lead auditor/audit team at least 20 days before audit
 |
| 1. Initial audit, reporting and follow-up
 | 2.1 Initial audit | * Full-scope initial ICC audit
 |
| 2.2 Reporting and follow-up | * Preparation and finalization of audit report by lead auditor/audit team and audit findings and CAPA (with relevant sections filled-in) sent to facility within a maximum of 20 working days post-audit via NAC.
	+ Facility completes CAP with RCA and proposed dates to complete action within 30 working days.
	+ Facility sends completed CAP, RCA to lead auditor/audit team via NAC for review of completeness and to determine if actions are appropriate and timely.
		- Lead auditor/audit team communicates with facility via NAC should additional actions be needed (within 10 working days) with facility providing response to lead auditor/audit team (within 10 working days), if needed
* Agreement on corrective actions reached by lead auditor/audit team and facility and approved by NAC.
* Implementation of corrective actions as per timeframes and requirements described in the CCS for NC1, NC2 and ICC - NC
* Verification of corrective action, evidence of action taken, reasons actions considered effective to address root-causes and prevent recurrence or where applicable an agreed plan in place for closure to address NC1 and NC2 as described in the CCS.
 |
| 1. Review and approval
 | * Technical review of overall audit conduct and findings by NAC in view of recommending the issuance of ICC
* NAC sends to GCC – CWG technical review outcome, recommendation for the issuance of an ICC, audit report, audit findings and CAP (list of identified NCs and time-bound action plan together with risk assessments and any other supporting documents, etc.
* Review of ICC application package submission by GCC – CWG and feedback provided to NAC
* GCC-countersigned ICC awarded
* NAC informs facility
 |
| 1. Monitoring and Renewal
 | * NAC monitors progress on the ICC-NC improvement plans as well any outstanding NCs.
* ICC Year 2 periodic audit (reduced scope audit)&
* ICC Year 3 periodic audit (reduced scope audit) &
 |
| Certificate of Containment (CC)§ | 1. Reporting, Review and Approval
 | * NAC submits evidence to GCC indicating all NCs including ICC – NCs have been effectively closed¶.
* Facility CC application submitted to GCC – CWG with recommendation for the endorsement of a CC
* GCC - CWG reviews submission, endorses the issuance of CC by NAC or recommends withhold/delay the issuance of the CC.
* Review of CC application package submission by GCC – CWG and feedback provided to NAC
* GCC-countersigned CC awarded
* NAC informs facility
 |
| 1. Monitoring
 | * CC Year 2 periodic audit (reduced scope audit)
* CC Year 3 periodic audit (reduced scope audit)
 |
| 1. Renewal
 | * Full-scope CC audit
* Facility CC re-certification application submitted to GCC – CWG with recommendation for the endorsement of a CC re-certification
 |
| \*An ICC application can be submitted when all NC1s have been effectively closed and verified and an agreed plan in-place for closure of ICC – NCs and NC2s in line with the requirements and timeframes described in the CCS. & Please indicate if an annual periodic audit is to be used to submit a CC application following the an audit with scope appropriate for the submission of a CC application (i.e. verification of closure of outstanding NCs). ¶From 1 January 2024, all CCS audit activities must be carried out against GAPIV. For facility ICC issued against GAPIII before 1 January 2024, a full-scope audit against GAPIV is required for a facility CC application. §For facility CC applications submission directly following the award of a CP, the process described under ICC should be followed. A CC application can be submitted when all NCs including ICC – NC have been effectively closed and verified or no nonconformities were identified during the initial audit.  |

1. The timelines to achieve the containment requirements\* for the certification of WPV eradication by end-2026 will remain in place independent of the status of eradication¶ . As such and for facilities to meet this requirement, all CCS certificate types issued before a CC should be of the shortest possible duration§.

\*Safe and secure containment of WPV retained in facilities, such as laboratories and vaccine manufacturing facilities - all facilities retaining WPVs should have a Containment Certificate, or an Interim Containment Certificate, with a clear end-point for obtaining a CC agreed with the GCC. (Source: Report of the 17th meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, 26-27 February 2018, Geneva, Switzerland. Available at: <https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf>)

¶ Report of the 24th meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, 22-23 November 2023, Geneva, Switzerland. Available at: [https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification- commission/](https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-%20commission/))

§Special Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis on Poliovirus Containment, 23-25 October 2017, Geneva, Switzerland. Available at: <https://polioeradication.org/wp-content/uploads/2018/03/polio-global-certification-commission-report-2017-10-20180314-en.pdf>) [↑](#footnote-ref-1)