

## **Poliovirus containment**

# CONTAINMENT WORKING GROUP OF THE GLOBAL CERTIFICATION COMMISSION (GCC-CWG)

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## TERMS OF REFERENCE

Applicable as of January 2024

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## ABBREVIATIONS AND ACRONYMS

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CAPA	Corrective and preventive action plan
CCS	Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment (GAPIII)
CC	Certificate of containment
CP	Certificate of participation in the containment certification scheme
CWG	Containment Working Group of the Global Commission for the Certification of the Eradication of Poliomyelitis
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use, 2015
GAPIV	Global Action Plan for Poliovirus Containment, 4th unedited edition, 2022
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPCAP	Global Poliovirus Containment Action Plan 2022-2024
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
IM	Infectious material
NAC	National authority for containment
NC	Nonconformity
nOPV	Novel oral poliomyelitis vaccine
nOPV2	Novel oral poliomyelitis vaccine type 2
OPV	Oral poliomyelitis vaccine
OPV2	Oral poliomyelitis vaccine type 2
PEF	Poliovirus-essential facility
PIM	Potentially infectious material
POL	Polio Eradication Department at the World Health Organization
PV	Poliovirus
RCA	Root cause analysis
TBAP	Time-bound action plan
VDPV	Vaccine-derived poliovirus
WHO	World Health Organization
WPV	Wild poliovirus

# 1. BACKGROUND

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Poliovirus containment is Goal One of the *Poliovirus Post-Certification Strategy* (PCS). Achieving and sustaining the restricted, safe, and secure handling or storing of polioviruses in laboratories, vaccine manufacturing sites, and other facilities (such as repositories) is key to preventing their release and reintroduction in a polio-free world.

The key focus areas include the reduction of the number of facilities storing or handling poliovirus globally and implementation and monitoring of appropriate biorisk management systems in facilities that retain poliovirus.

Steps towards reaching global poliovirus containment include:

1. Risk elimination:
  - a. Inventory and destruction of poliovirus infectious and potentially infectious materials (PV IM and PIM):
    - i. Identification of remaining stocks of PV IM and PIM
    - ii. Destruction of unneeded PV IM and PIM
    - iii. Transfer of needed PV IM or WPV/VDPV PIM<sup>1</sup> to a poliovirus-essential facility (PEF).
2. Biorisk management:
  - a. Containment of needed PV materials:
    - i. Implementation of the biorisk management system described in *WHO Global Action Plan for Poliovirus Containment, 4<sup>th</sup> edition, 2022* (GAPIV)<sup>2</sup>, thus demonstrating minimization of the risk of a containment breach potentially leading to the reintroduction of poliovirus into the population
3. Containment certification:
  - a. Facilities retaining polioviruses must receive certification against the implementation of GAPIV by NACs, with global oversight by the GCC, in line with the *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment* (CCS)<sup>3</sup>.

To meet the containment goal, WHO published GAPIV, providing the reference standard facilities handling or storing PV IM or WPV/VDPV PIM are required to meet. In alignment with the latest version of GAP (GAPIV) the containment certification scheme (GAPIII-CCS, hereafter referred to as the CCS) is being revised to assist national authorities for containment (NACs) in their efforts to assess facilities and certify that they meet the required biorisk management standard, assuring the global community that risks associated with the retention of polioviruses are appropriately managed, controlled and minimized.

CCS describes three types of containment certificates:

1. Certificate of participation in the containment certification scheme (CP)
2. Interim certificate of containment (ICC)
3. Certificate of containment (CC)

Please refer to Annex A for facilities' eligibility for containment certification.

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<sup>1</sup> Pending revision of the *Poliovirus containment: guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for polioviruses, second edition* (PIM Guidance, <https://iris.who.int/bitstream/handle/10665/341367/9789240021204-eng.pdf>, accessed on 1 March 2024)

<sup>2</sup> Pending finalization of GAPIV (<https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>, accessed on 1 March 2024)

<sup>3</sup> Pending revision of the *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment* (CCS, [https://polioeradication.org/wp-content/uploads/2017/11/CCS\\_19022017-EN.pdf](https://polioeradication.org/wp-content/uploads/2017/11/CCS_19022017-EN.pdf), accessed on 1 March 2024)

## 2. CWG ROLE

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The Containment Working Group of the Global Certification Commission of the Eradication of Poliomyelitis (GCC-CWG, hereafter referred to as the CWG):

1. reviews applications to ensure a designated PEF is eligible<sup>4</sup> to join the containment certification process
2. approves/endorse the process to award and maintain containment certificates (CP, ICC, CC), following CCS
3. reviews and recommends GCC to approve national reports on containment activities based upon information supplied through the GCC-endorsed process (following the CCS)
4. recommends GCC to approve/endorse the issuance of containment certificates (CP, ICC, CC) submitted by NACs following the CCS process.

CWG supports GCC in its role as the global containment oversight body that confirms the global containment of polioviruses.

Facilities retaining (handling or storing) PV IM or WPV/VDPV PIM must hold valid containment certificates (following CCS and GCC's recommended timelines<sup>5</sup>), issued by the NAC and countersigned by GCC. Facilities can only hold one valid certificate at a time: facilities obtaining an ICC lose their CP, facilities obtaining a CC lose their ICC.

All CWG members familiarize themselves with documentation provided by NACs, or PEFs through NACs, and participate in discussions on specific applications.

CWG members will not participate in the evaluation of any CP/ICC/CC submission related to their country(-ies) of origin or residence.

Please refer to Annex B for the list of activities/responsibilities CWG is expected to cover.

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<sup>4</sup> For more details, please refer to *Annex 1: Facilities' eligibility for containment certification* in this document.

<sup>5</sup> Pending the publication of the latest GCC mtg report (Nov 2023)

### 3. CWG COMPOSITION

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The CWG has up to 11 members, selected through calls for nomination and appointed by the Director WHO/POL, in consultation with GCC.

Members represent the broad range of disciplines relevant to poliovirus containment described in CCS, and eligible members are expected to provide, as minimum, expertise in one or more of the following areas:

1. Management system auditing
2. Biorisk management
3. Risk assessment
4. Vaccine production and storage
5. Laboratory science and work
6. High-containment engineering
7. Biosafety
8. Biosecurity
9. Poliovirus virology
10. Communicable disease prevention and control

WHO selects the CWG Chair, in consultation with GCC. The CWG Chair may be a member of GCC and is appointed for 3 years with the possibility of renewal(s), as approved by the Director WHO/POL, in consultation with GCC.

At least two thirds of the GCC-CWG members must be present during TCs or in-person meetings to meet a quorum.

Members of the CWG are appointed to serve for a period of 3 years with the possibility of renewal(s), as approved by the Director WHO/POL, in consultation with GCC and the CWG Chair.

CWG members sign WHO's declaration of interest (DOI) form and the confidentiality undertaking (COU) at the beginning of every third calendar year and respect the impartiality, independence and discretion required by WHO.

In performing their work, CWG members do not seek or accept instructions from any Government or authority external to WHO, including, e.g., their employers or other possible influencers.

CWG members are free of any conflict of interest, real, potential, or apparent, and:

1. Do not have any financial relationship with a PEF or a NAC as an employee for the previous three years
2. Are not members of the containment advisory group (CAG), the polio research committee (PRC), the global polio laboratory network (GPLN), the Strategic Advisory Group of Experts on Immunization (SAGE), or any other poliovirus containment-related advisory group established by the Global Polio Eradication Initiative (GPEI) or its individual members.

The CWG Chair (or a CWG delegate) participates in meetings of the GCC, CAG and of the Chairs of Advisory Groups related to poliovirus containment to ensure smooth, transparent, and efficient communication between groups.

# ANNEX 1: FACILITIES' ELIGIBILITY FOR CONTAINMENT CERTIFICATION

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## A1.1. Certificate of participation (CP)

### Eligibility to achieve a CP:

Eligibility for a facility to enter the certification process and be awarded a certificate of participation (CP) is determined when:

- The hosting country/NAC has provided evidence that the immunization coverage (i.e.,  $\geq 90\%$  IPV1 or IPV2 coverage pre-OPV cessation;  $\geq 90\%$  IPV2 coverage post-OPV cessation) and environmental safeguards (i.e., PEFs are located in areas with closed sewage systems with a minimum of secondary treatment of effluents, with low population density, with demonstrated low faecal-oral disease transmission) described in GAPIV<sup>6</sup> are met
- The facility has provided a plausible reason for the retention of poliovirus materials
- The facility is designated as a PEF by a national authority
- The facility has stated the conditions for PV containment in the period prior to issuance of an ICC/CC
- The facility has the potential to meet the facility safeguards described in GAPIV
- The facility has provided a time-bound action plan specifying the proposed measures to achieve ICC status or cease work with PV material requiring containment

### Eligibility to extend the validity of a CP:

In line with the CCS and GCC recommendations, eligibility for a CP-holding facility to extend the validity of its CP is determined when:

- The NAC is ready to organize GAP/CCS audits
- The facility has submitted an updated CP application form if changes apply to the previous submission
- The facility has submitted a time-bound action plan specifying expected timelines for achieving an ICC or ceasing work with relevant PV materials requiring containment.

## A1.2. Interim Containment Certificate (ICC)

### Eligibility to achieve an ICC:

Eligibility for a CP-holding facility to be certified against the implementation of GAPIV following CCS and be awarded an interim certificate of containment (ICC) is determined when:

- The hosting country/NAC has provided evidence that the immunization coverage (i.e.,  $\geq 90\%$  IPV1 or IPV2 coverage pre-OPV cessation;  $\geq 90\%$  IPV2 coverage post-OPV cessation) and environmental safeguards (i.e., PEFs are located in areas with closed sewage systems with a minimum of secondary treatment of effluents, with low population density, with demonstrated low faecal-oral disease transmission) described in GAPIV are met<sup>6</sup>
- The audit team is composed of qualified GAPIV/CCS auditors and technical experts, covering all required areas of expertise as described in CCS
- The NAC is ready to organize periodic audits within 12 months of the initial audit, following the three-year audit cycle described in CCS

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<sup>6</sup> Strategy, GAPIV, page 27 (<https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>, accessed 1 March 2024)

- The facility has been assessed and determined to be broadly compliant with the facility safeguards described in GAPIV but cannot meet all the requirements. However, these facilities have demonstrated that adequate alternative control measures, identified through risk assessments, are in place for work with PV while action is taken to address the need for full conformity or to cease work with PV materials requiring containment.
- The NAC has reviewed and approved the facility's risk assessments, demonstrating that adequate alternative control measures are in place for work with poliovirus while action is taken to address the need for full conformity or to cease work to a defined timescale
- The facility has developed root cause analyses, corrective and preventive action plans, and closed all NCs (except for ICC-NCs<sup>7</sup>) raised in the initial audit, as defined in the CCS
- The facility has developed and follows a NAC-approved time-bound action plan (TBAP) to close all identified ICC-NCs
- The NAC monitors progress on the agreed improvement plan for all ICC-NCs. If the improvement plan is not adhered to, the CWG should recommend suspending or withdrawing the ICC and require work to cease.

#### Eligibility to extend the three-year validity of an ICC:

Eligibility for an ICC-holding PEF to extend the validity of its ICC is determined when:

- The hosting country continues to meet the immunization coverage and environmental safeguards described in GAPIV
- The audit team is composed of qualified GAPIV/CCS auditors and technical experts, covering all required areas of expertise as described in CCS
- The facility has successfully completed two periodic audits after the initial audit, within 12 months of the previous audit, following CCS
- The facility has plausible reasons that have prevented its ability to close all ICC-NCs by the end of the first ICC's 3-year cycle, approved by the NAC
- The facility has any other extenuating circumstances, approved by the NAC
- The facility has plausible reasons that prevents it from achieving a CC

#### Eligibility to renew the three-year validity of an ICC:

ICC-holding PEFs are expected to apply for a CC after the first cycle of ICC validity (3 years). The option of renewing ICCs is not available. ICC-holding PEFs are expected to apply for a full containment certificate (CC) after the first 3-year ICC cycle.

be audited against all elements of the biorisk management system described in GAPIV and determined to be compliant with all requirements set out in GAPIV as determined by a competent, independent team of auditors, to achieve a).

### A1.3. Containment Certificate (CC)

#### Eligibility to achieve a CC

Eligibility for an ICC-holding PEF to be awarded a full certificate of containment (CC) is determined when:

- The hosting country/NAC has provided evidence that the immunization coverage (i.e., ≥90% IPV1 or IPV2 coverage pre-OPV cessation; ≥90% IPV2 coverage post-OPV cessation) and

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<sup>7</sup> An ICC-NC is an NC that cannot be closed due to the need of major structural work or for other similar reasons, thus preventing the issuance of a full CC (page 7, [https://polioeradication.org/wp-content/uploads/2017/11/CCS\\_19022017-EN.pdf](https://polioeradication.org/wp-content/uploads/2017/11/CCS_19022017-EN.pdf), accessed on 1 March 2024)



environmental safeguards (i.e., PEFs are located in areas with closed sewage systems with a minimum of secondary treatment of effluents, with low population density, with demonstrated low faecal-oral disease transmission) described in GAPIV are met<sup>6</sup>

- The audit team is composed of qualified GAPIV/CCS auditors and technical experts, covering all required areas of expertise as described in CCS
- The NAC is ready to organize periodic audits within 12 months of the initial audit, following the three-year audit cycle described in CCS
- The facility has closed all NCs raised in the initial audit
- The facility has been assessed and determined by a competent, independent team of auditors to meet all facility safeguards described in GAPIV, following CCS

#### Eligibility to renew the three-year validity of a CC:

Eligibility for a CC-holding PEF to renew the validity of its CC is determined when:

- The hosting country continues to meet the immunization coverage and environmental safeguards described in GAPIV
- The audit team is composed of qualified GAPIV/CCS auditors and technical experts, covering all required areas of expertise as described in CCS
- The facility has successfully completed two periodic audits after the initial audit, within 12 months of the previous audit, following CCS
- The facility has closed all NCs raised in the initial audit
- The facility has been assessed and determined by a competent, independent team of auditors to meet all facility safeguards described in GAP, following CCS.

## ANNEX 2: CWG ACTIVITIES AND RESPONSIBILITIES

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### A2.1. Certificate of participation (CP)

#### CP applications

CWG reviews and processes the CP applications submitted to GCC via the CWG Secretariat and CWG by the designated poliovirus-essential facilities (PEFs) through their respective national authorities for containment (NACs), to ensure their eligibility in the certification process described in the CCS. The following steps must be implemented:

1. NACs approve and submit designated PEFs' CP applications to the CWG Secretariat at WHO. To be accepted by CWG (and GCC), each CP application must include:
  - i. Evidence that the designated PEF's hosting country meets immunization coverage (i.e.,  $\geq 90\%$  IPV1 or IPV2 coverage pre-OPV cessation;  $\geq 90\%$  IPV2 coverage post-OPV cessation) and environmental safeguards (i.e., PEFs are located in areas with closed sewage systems with a minimum of secondary treatment of effluents, with low population density, with demonstrated low faecal-oral disease transmission) described in GAPIV.<sup>6</sup>
  - ii. Rationale for the designated PEF to retain poliovirus materials
  - iii. A description of retained PV materials
  - iv. A description of the conditions for PV containment in the period prior to the issuance of an ICC/CC
  - v. Preliminary evidence that the designated PEF can meet GAPIV requirements
  - vi. A NAC-approved, designated PEF's time-bound action plan to achieve Interim Certificate of Containment (ICC) or to cease poliovirus work through documented evidence of virus transfer or destruction
  - vii. The NAC's ICC audit plan, providing the list of auditors and their CVs, details of the audit team composition, and an indication of when the full-scope initial audit is planned to take place.
  - viii. The NAC's recommendation to award a CP
2. Upon verification that all requested documentation<sup>8</sup> has been supplied, the CWG Secretariat shares the complete CP applications with the CWG for technical review
3. A team of CWG members selected by the CWG Chair, comprising expertise in all required areas, independently evaluates each CP application
4. The CWG Chair provides the CWG Secretariat with the final CWG assessment (i.e., accepted, requiring more information, rejected) and explanation for the decision at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission of the CP application to the CWG Secretariat
5. NACs are requested to provide any additional information before the following CWG monthly TC or quarterly in-person meeting<sup>9</sup>
6. CWG evaluates the additional information at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following its submission
7. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, PEF, relevant technical experts), the latter shortly after the CWG monthly TC or quarterly in-person meeting during which discussions were held.
8. When the CWG team is in agreement, the CWG Secretariat provides a summary report of CWG discussions in Part C of the CP application. The CWG Chair signs it off and recommends the GCC

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<sup>8</sup> CCS forms and templates (<https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-certification-scheme-forms-and-templates/>, accessed 1 March 2024)

<sup>9</sup> Whichever comes first

- Chair to approve, endorse and countersign the application for certificate of participation (CP).
9. The CWG Secretariat then informs the NAC of GCC's conclusions.
  10. As of April 2024, no new CPs will be granted. PEFs requiring containment certification after this deadline will have to apply for ICC directly.

### CP extensions

1. In the past, CWG has extended the duration of CPs beyond the original 1 year + two 3-months periods, following CCS deviations agreed by GCC<sup>10, 3</sup>.
2. As of January 2024, no CP extensions will be granted.
3. However, at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> held after end-March 2024, CWG will consider an alternate duration of CP validity if:
  - a. PEFs communicate to CWG via the NAC and CWG Secretariat all changes to the original CP
  - b. the NAC submits their ICC audit plan by end-March 2024, for CWG's approval by end-June 2024
  - c. PEFs plan to cease poliovirus work by end-June 2024

### CP suspensions

1. CWG, in consultation with the NAC, should request the suspension of a designated PEF's CP and require the facility to stop work with live PV material requiring containment when the facility holds an expired CP and, by end-June 2024:
  - a. a facility that had planned to cease work with poliovirus requiring containment has not yet done so
  - b. CWG has not yet approved the NAC's ICC audit plan
2. The CWG Secretariat informs the NAC of CWG's request to suspend the CP
3. The NAC informs the PEF of the CP suspension and submits the PEF's confirmation that work with PV materials is temporarily stopped
4. Upon verification that all requested documentation has been supplied, the CWG Secretariat shares the relevant documentation with CWG
5. If CWG is in agreement, the CWG Chair recommends that GCC note the suspension of the CP
6. GCC revokes CP suspensions as soon as it approves the NAC's ICC audit plan

### CP terminations

1. The NAC terminates a designated PEF's CP when the facility ceases work with PV and documents the destruction of remaining PV materials or their transfer to an ICC/CC-holding PEF
2. The NAC informs the CWG Secretariat of the CP termination and submits the PEF's documented evidence of destruction or transfer of all PV materials to the CWG Secretariat
3. Upon verification that all requested documentation has been supplied, the CWG Secretariat shares the complete CP termination files with the CWG for final review
4. If CWG is in agreement, the CWG Chair recommends GCC to note the termination of the CP and remove the facility from the list of facilities retaining PV materials.

### CP withdrawals

1. The NAC revokes a designated PEF's CP when the facility
  - a. Violates the terms of the certificate
  - b. Experiences an unauthorized release of PV material

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<sup>10</sup> Global Polio Eradication Initiative. Report from the Twenty-first Meeting of the Global Commission for Certification of Poliomyelitis Eradication. Geneva: GPEI; July 2021 (<https://polioeradication.org/wp-content/uploads/2021/09/21st-GCC-report-20210906.pdf>, accessed 1 March 2024).

- c. Requests a withdrawal
2. The NAC requests that work with PV be stopped until the situation is restored
3. The NAC informs the CWG Secretariat of the CP withdrawal and the request for the facility to stop work with PV materials
4. The CWG Secretariat shares the complete CP withdrawal files with the CWG for review
5. If CWG is in agreement, the CWG Chair recommends GCC to note the withdrawal of the CP
6. After a withdrawal, a CP can only be reassigned after a new approved CP application
7. If the PEF has no intention to further retain PV materials and apply for a new CP, a CP termination must be followed.

## A2.2. Interim Containment Certificate (ICC)

### Applications for interim certificate of containment (ICC)

CWG reviews and processes the ICC applications submitted to GCC via the CWG Secretariat and CWG by CP-holding PEFs that have been found by their NAC to be broadly compliant with the containment requirements described in GAPIII/IV and have demonstrated that alternative controls are in place for work with poliovirus while action is taken to address the need for full conformity or to cease work to a defined timescale.

The timing for individual steps should allow the NAC/PEF to meet the deadlines described in the *Global Poliovirus Containment Action Plan (GPCAP) 2022-2024*<sup>11</sup> or any deviation accepted by GCC<sup>12</sup>.

The following steps must be implemented:

### Preparations for ICC audits

#### A. ICC audit team approval

1. NACs provide candidate GAP/CCS auditors' CVs for CWG's approval
2. A team of CWG members individually evaluates each candidate GAP/CCS auditor's CV, following a set of harmonized, globally applicable, and published criteria<sup>3</sup> as recommended by GCC<sup>9</sup>, based on:
  - a. Competency records<sup>13</sup> as auditors/technical experts in related fields
  - b. Experience (GPEI-provided GAP/CCS training records and related achievement certificates; attendance of advanced auditor training (AAT), etc.)
3. The CWG Chair provides the CWG Secretariat with the final CWG assessment of the candidate auditors (accepted, requiring more information, rejected) and explanation for the decision at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission of the ICC application to the CWG Secretariat
4. The CWG Secretariat requests NACs to provide any additional information before the following CWG monthly TC or quarterly in-person meeting<sup>9</sup>, or in time to allow PEFs/NACs to meet the deadlines to award ICCs described in the GPCAP or any deviations accepted by the GCC<sup>12</sup>
5. CWG evaluates the additional information at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following its submission
6. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, auditors, technical experts), the latter shortly after the CWG monthly TC or quarterly in-person meeting<sup>9</sup> during which discussions were held.
7. If CWG is in agreement, the CWG Chair approves the auditors during the first CWG monthly TC

<sup>11</sup> Figure 2, *Global Poliovirus Containment Action Plan 2022-2024*, page 5 (<https://polioeradication.org/wp-content/uploads/2022/07/GPCAP-2022-2024.pdf>, accessed 1 March 2024)

<sup>12</sup> GCC meeting reports (<https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/>, accessed 1 March 2024)

<sup>13</sup> Summary of training and experience, as described in the CV

or a quarterly in-person meeting<sup>9</sup> following the submission.

#### B. ICC audit plan approval

1. NACs submit to CWG the time-bound audit plan to achieve an ICC, agreed to with the CP-holding PEF
2. A team of CWG members individually evaluates the plan. The CWG Chair provides the CWG Secretariat with the final CWG assessment for the audit plan (i.e., accepted, requiring more information, rejected) and explanation for the decision at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission of the ICC application to the CWG Secretariat.
3. NACs/PEFs are requested to provide any additional information before the following CWG monthly TC or quarterly in-person meeting<sup>9</sup>, or latest in time to allow PEFs/NACs to meet the deadlines to award ICCs described in the GPCAP or any deviations accepted by the GCC<sup>5</sup>
4. CWG evaluates the additional information at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following its submission
5. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, PEF, technical experts), the latter shortly after the CWG monthly TC or quarterly in-person meeting<sup>9</sup> during which discussions were held.
6. If CWG is in agreement, the CWG Chair approves the audit plan during a CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission.

#### GAP/CCS ICC audit and certification

1. Before expiry of the CP, NACs approve and submit the ICC applications by CP-holding PEFs to the CWG Secretariat at WHO. To be accepted, each ICC application must include evidence that the NAC has organized a GAP/CCS audit with competent auditors and approved the initial ICC audit report, ensuring
  - a. CWG approved the audit team members
  - b. the audit team appropriately classified its findings according to available guidance<sup>14</sup>
  - c. the NAC has approved all root cause analyses and corrective and preventive action plans (RCA/CAPAs) for all raised NCs
  - d. the facility addressed and closed all identified nonconformities (NCs)
  - e. the NAC approved all facility's risk assessments (RAs), including those addressing the ICC-NCs and related alternative control measures
  - f. the NAC approved the facilities' time-bound plans to close all ICC-NCs within a reasonable time<sup>15</sup>
  - g. the NAC determined that the facility is broadly compliant with GAPIV (except for the ICC-NCs)
  - h. the NAC recommends the award of an ICC
2. A team of CWG members selected by the CWG Chair, comprising expertise in all required areas, evaluates each ICC application, including the audit report, all associated risk assessments, root cause analyses and corrective and preventive action plans, and closure of NCs.
3. The CWG Chair provides the CWG Secretariat with the final CWG assessment (i.e., accepted, requiring more information, or rejected) and explanation for the decision at the first CWG quarterly in-person meeting following the submission of the ICC application to the CWG Secretariat.
4. The CWG Secretariat requests NACs to supply the additional information to the CWG Secretariat before its next CWG monthly TC or quarterly in-person meeting<sup>9</sup>.
5. CWG evaluates the provided additional information at the first CWG monthly TC or quarterly

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<sup>14</sup> Pending revision of the audit report template (<https://polioeradication.org/wp-content/uploads/2023/06/03-ICC-Audit-Report-Template-2022-10.pdf>, accessed 1 March 2024)

<sup>15</sup> The duration of an ICC is limited to a maximum period of three years. An ICC-holding PEF is expected to achieve a full CC within this timeframe.

- in-person meeting<sup>9</sup> following its submission to the CWG Secretariat.
6. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, PEF, technical experts), the latter shortly after the CWG monthly TC or quarterly in-person meeting<sup>9</sup> during which discussions were held.
  7. When the CWG team is in agreement, the CWG Secretariat provides a summary report of CWG discussions in Part C of the ICC application. The CWG Chair signs it off and recommends the GCC Chair to approve, endorse and countersign the application for interim containment certificate (ICC).
  8. The CWG Secretariat then informs the NAC of GCC's conclusions.

### ICC validity and renewals

1. An ICC is issued following the successful completion of the initial full scope certification audit against all elements specified in Annex 2 or 3 of GAPIII, or the Annex in GAPIV,
2. ICCs have a validity of 3 years from the date of issuance.
3. The NAC monitors progress on the agreed time-bound plan for all ICC-NCs on a quarterly basis
4. Within one year and two years after the initial audit, NACs approve and submit the ICC applications for the periodic audits, following the same process as for original applications
5. ICCs may only be extended for up to 12 months provided a reasonable justification for not closing the ICC-NCs within the allowed period of three years.
6. CWG evaluates periodic audit results from ICC-holding PEFs following the same process as for original applications.
7. No renewals of ICCs will be granted.
8. Facilities must apply for a CC latest by the end of the first ICC 3-year cycle (and additional 12 months extension, if granted).

### ICC terminations

5. The NAC terminates a PEF's ICC when the facility ceases work with PV materials requiring containment and confirms the destruction of remaining PV materials or their transfer to an ICC/CC-holding PEF
6. The NAC informs the CWG Secretariat of the ICC termination and submits the PEF's evidence of destruction or transfer of all PV materials requiring containment
7. Upon verification that all requested documentation has been supplied, the CWG Secretariat shares the complete ICC termination files with the CWG for final review
8. If CWG is in agreement, the CWG Chair recommends GCC to note the termination of the ICC and remove the facility from the list of facilities retaining PV materials.

### ICC withdrawals

1. The NAC revokes a PEFs' ICC when the facility (see CCS):
  - a. Violates the terms of the certificate
  - b. Experiences a major breach of compliance with GAP or of associated certification requirements
  - c. Requests a withdrawal
2. The NAC requests that work with PV be stopped until the situation is restored
3. The NAC informs the CWG Secretariat of the ICC withdrawal and provides documented evidence that the facility has stopped work with PV materials requiring containment
4. The CWG Secretariat shares the complete ICC withdrawal files with the CWG for review
5. If CWG is in agreement, the CWG Chair recommends GCC to note the withdrawal of the ICC
6. After a withdrawal, an ICC can only be reassigned after a new full initial GCC/CCS audit.

## A2.3. Containment Certificate (CC)

### CC applications

CWG reviews and processes the CC applications submitted to GCC via the CWG Secretariat and CWG by ICC-holding facilities that have been found by their NAC to be fully compliant with the containment requirements described in GAPIV.

A CC can be issued as an upgrade to an ICC once the PEF presents evidence to the NAC and GCC/CWG that all outstanding ICC-NCs have been closed and all GAP requirements have been met.

If the ICC is upgraded to a CC during the three-year period covered by the ICC, the certification cycle remains unchanged.

The following steps must be implemented:

### Preparations for CC audits

#### CC audit team approval

1. NACs provide GAP/CCS audit team members' CVs for CWG's approval
2. A team of CWG members individually evaluates each GAP/CCS lead auditor/auditor's CV based on CCS<sup>3</sup>, possibly including:
  - a. Competency records as auditors in related fields (mandatory: internationally recognized management system auditor accreditation, and
  - b. Experience (mandatory: GPEI-provided GAP/CCS training records and related achievement certificates; Advanced auditor training (AAT); gap assessments or mock audits at designated PEFs. Desirable: previous GAP audits, etc.)
3. A team of CWG members evaluates each technical expert's CV based on:
  - a. Competency records in competency-related fields, following CCS
  - b. Experience, following CCS
4. The CWG Chair provides the CWG Secretariat with the final CWG assessment of the audit team (i.e., accepted, requiring more information, rejected) and explanation for the decision at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission of the CP application to the CWG Secretariat.
5. The CWG Secretariat requests NACs to provide any additional information before the following CWG monthly TC or quarterly in-person meeting<sup>9</sup>
6. CWG evaluates the additional information at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following its submission
7. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, audit team members), the latter shortly after the CWG monthly TC or quarterly in-person meeting<sup>9</sup> during which the discussion was held.
8. If CWG is in agreement, the CWG Chair approves the audit team members for their indicated specific roles (lead auditor, auditor, technical expert, observer, translator, etc.), following CCS

#### GAP/CCS CC audit and certification

1. Before expiry of the ICC, NACs approve and submit the CC applications by ICC-holding PEFs to the CWG Secretariat at WHO. To be accepted, each CC application must include evidence that the PEF closed all outstanding ICC-NCs, and the NAC organized a GAP/CCS audit with competent auditors and approved the initial CC audit report, ensuring
  1. CWG approved the audit team members
  2. the audit team appropriately classified its findings according to available guidance<sup>13</sup>
  3. the NAC approved all root cause analyses and corrective and preventive action plans (RCA/CAPAs) for all raised NCs
  4. the facility addressed and closed all identified nonconformities (NCs)
  5. the NAC approved all facilities' risk assessments (RAs)
  6. the NAC determined that the facility is fully compliant with GAPIV



7. the NAC recommends the award of a CC
2. A team of CWG members selected by the CWG Chair, comprising expertise in all required areas, evaluates each CC application, including the audit report, all associated RAs, RCAs and CAPAs, and the closure of NCs.
3. The CWG Chair provides the CWG Secretariat with the final CWG assessment (i.e., accepted, requiring more information, or rejected) and explanation for the decision at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following the submission of the ICC application to the CWG Secretariat.
4. The CWG Secretariat requests NACs to supply the additional information to the CWG Secretariat before its next CWG monthly TC or quarterly in-person meeting<sup>9</sup>.
5. CWG evaluates the provided additional information at the first CWG monthly TC or quarterly in-person meeting<sup>9</sup> following its submission to the CWG Secretariat.
9. In case of disagreement, discussions within the full CWG resolve the differences, in consultation with the CWG Secretariat and WHO, and if necessary other relevant stakeholders (NAC, PEF, technical experts), the latter shortly after the CWG monthly TC or quarterly in-person meeting<sup>9</sup> during which discussions were held.
10. When the CWG team is in agreement, the CWG Secretariat provides a summary report of CWG discussions in Part C of the CC application. The CWG Chair signs it off and recommends the GCC Chair to approve, endorse and countersign the application for a full containment certificate (CC).
11. The CWG Secretariat then informs the NAC of GCC's conclusions.

### CC validity and renewals

1. CCs have a validity of 3 years from the date of issuance.
2. A CC is issued following the successful completion of the initial full scope certification audit against all elements specified in Annex 2 or 3 of GAPIII, or the Annex in GAPIV
3. Within one year and two years after the initial audit, NACs approve and submit the ICC applications for the periodic audits, following the same process as for original applications
4. CWG evaluates periodic audit results from CC-holding PEFs following the same process as for original applications.
5. A CC is valid for three years, part of which may encompass the upgrade of the certificate from ICC to CC
6. Facilities must apply for a CC latest by the end of the first ICC 3-year cycle (and additional 12 months extension, if granted).
7. A CC full-scope GAP audit is repeated at the end of the three-year cycle. Successful completion will result in the renewal of the CC for a further three years

### CC terminations

9. The NAC terminates a PEF's CC when the facility ceases work with PV materials requiring containment and confirms the destruction of remaining PV materials or their transfer to an CC-holding PEF
10. The NAC informs the CWG Secretariat of the CC termination and submits the PEF's evidence of destruction or transfer of all PV materials requiring containment
11. Upon verification that all requested documentation has been supplied, the CWG Secretariat shares the complete CC termination files with the CWG for final review
12. If CWG is in agreement, the CWG Chair recommends GCC to note the termination of the CC and remove the facility from the list of facilities retaining PV materials.

### CC withdrawals

7. The NAC revokes a PEFs' ICC when the facility (see CCS):
  - a. Violates the terms of the certificate



- b. Experiences a major breach of compliance with GAP or of associated certification requirements
  - c. Requests a withdrawal
- 8. The NAC requests that work with PV be stopped until the situation is restored
- 9. The NAC informs the CWG Secretariat of the CC withdrawal and provides documented evidence that the facility has stopped work with PV materials requiring containment
- 10. The CWG Secretariat shares the complete CC withdrawal files with the CWG for review
- 11. If CWG is in agreement, the CWG Chair recommends GCC to note the withdrawal of the ICC
- 12. After a withdrawal, a CC can only be reassigned after a new full initial GCC/CCS audit.

As recommended by GCC<sup>5</sup>, PEFs are expected to achieve full containment certification (CC) status by end-2026, or at least hold a time-limited, GCC-agreed ICC.

## ANNEX C: CONTAINMENT CERTIFICATION TIMELINES

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Facilities are allowed to continue to store or work with PV materials if they hold valid certificates. However, respect for the following timelines is requested:

1. End-2023<sup>16</sup>: All facilities identified as retaining WPV/VDPV IM or PIM, or OPV2/Sabin2 IM, hold a valid CP
2. As of Jan 2024: facilities holding expired CPs must submit the ICC audit plan and seek CWG's approval, or their CP and activities with WPV/VDPV IM or PIM, or OPV2/Sabin2 IM, are suspended
3. End-March 2024: NACs have submitted ICC applications for all their PEFs to the CWG Secretariat
4. End-Dec 2026<sup>5</sup>: all facilities retaining WPV/VDPV IM or PIM, or OPV2/Sabin2 IM, hold a GCC-approved, time-bound ICC, or a CC, or their certificates and activities with PV are suspended

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<sup>16</sup> *Global Poliovirus Containment Action Plan 2022-2024* (<https://polioeradication.org/wp-content/uploads/2022/07/GPCAP-2022-2024.pdf>, accessed 1 March 2024)