

Global Certification Commission Containment Working Group (GCC-CWG)

Terms of Reference

Objective 3 of the *Polio Eradication & Endgame Strategic Plan 2013-2018* aims to ensure that all poliovirus stocks, as well as materials potentially contaminated with polioviruses, are either destroyed or safely and securely contained to minimise the risk of reintroduction of poliovirus into the population. This process is essential leading into the era of polio eradication whereby the containment of infectious and potentially infectious poliovirus materials is ensured.

To meet this objective, the WHO developed the GAPIII document: *Global Action Plan to minimise poliovirus facility-associated risk after the type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use*. This provides a reference standard to assist facilities potentially handling polioviruses, including laboratories and vaccine manufacturing facilities (collectively referred to as poliovirus essential facilities or PEFs), in their efforts to meet containment requirements under GAPIII. In alignment with GAPIII, a containment certification scheme (CCS) has been developed as a recommended step-wise system, to assist poliovirus essential facilities to meet the required standards for containment.

Under the GAPIII and the CCS, the Global Certification Commission (GCC) of the Eradication of Poliomyelitis, will review applications submitted from PEFs and certify that the implementation of GAPIII meets the required international standards. The GCC Containment Working Group (GCC-CWG) will assist the GCC in reviewing applications and approving/endorsing certificates.

Terms of Reference:

1. Members of the GCC-CWG will review the applications submitted by the PEFs to participate in the CCS. The PEFs will submit their applications to their respective National Authorities for Containment (NACs), in order to ensure their eligibility in the certification process. If eligibility is determined, the PEF will be issued a certificate of participation (CP):
 - a. NACs will submit the applications by PEFs to the WHO Secretariat, and each application should include:
 - i. Rationale for PEF to retain poliovirus materials
 - ii. Time plan to achieve Interim Certificate of Containment (ICC) or Certificate of Containment (CC) or the cessation of poliovirus work
 - iii. Proposed evaluation and monitoring activity
 - b. Upon review of completeness of the application, the WHO Secretariat will share the applications with the GCC-CWG for review
 - c. Two members of the GCC-CWG will evaluate each application, working as primary and secondary reviewers, and will provide the WHO secretariat with their assessment (i.e. accept, more information or reject) within 10 working days
 - d. GCC-CWG will approve and endorse a certificate (i.e. CP) on behalf of GCC, if both reviewers are in agreement. If the two reviewers disagree, the Chair will resolve the difference (e.g. e-mail, conference call)

2. Members of the GCC-CWG will review and process the applications for ICC, if a CP-holding PEF decides to apply for an ICC, rather than CC.
 - a. PEFs will submit their applications to their NACs for submission to the WHO Secretariat, and each application should include:
 - i. initial audit report
 - ii. Action plan for correction of non-conformities
 - iii. Risk assessment and recommendation of ICC issued from NAC
 - b. Members of the GCC-CWG will work as both primary and secondary reviewer for applications and present each application to other GCC-CWG members during a monthly teleconference
 - c. Members of the GCC-CWG will provide recommendations as an outcome of the teleconference regarding the endorsement of ICC and feedback to the NACs/PEFs. The WHO Secretariat will prepare a summary report of GCC-CWG discussions.
 - d. The GCC-CWG will approve and endorse a certificate (i.e. ICC) on behalf of GCC if the GCC-CWG recommends the endorsement of ICC
3. Members of the GCC-CWG will review and process the applications for the certification of containment (CC)
 - a. A CC may be issued directly to a CP holding PEF; in this case, the GCC-CWG will review the evidence in the application that all GAPIII criteria are met
 - b. A CC may also be issued as an upgrade from an ICC. In this case the GCC-CWG will review evidence that all non-conformities have been addressed, as well as review additional audit reports from reviewers
 - c. For the review of a CC, a similar process outlined in the approval/endorsement of the ICC will be followed (i.e. discussions during the monthly teleconference and the certificate approved and endorsed by the GCC-CWG)
4. As per the CCS requirements, review requests from PEF via NAC, to extend the duration of CP and ICC (e.g. based on evidence of extenuating circumstances)
 - a. CP may only be extended twice, up to 3 months per extension
 - b. ICC may be extended up to 12 months
 - c. The process to extend CP/ICC will follow the same process as original applications
5. Members of the GCC-CWG will support the CWG review, an additional assessment and summary report prepared by WHO secretariat for ICC/CC applications (and CP application if necessary)
6. Members of the GCC-CWG will participate in the conflict resolution process between GCC, NAC and PEF, as requested by the GCC
7. GCC-CWG chair (or CWG delegate) to participate in the Containment Advisory Group meetings to ensure smooth and efficient communication between groups when required.

Composition:

- The Chair of GCC-CWG will be selected by WHO from among GCC members, in consultation with the chair of the GCC
- The GCC-CWG will have up to 7 members, selected through a call for nominations and appointed by the Director, POL, WHO. Members will represent the broad range of disciplines relevant to poliovirus containment, and eligible members include:
 - Experts from National Regulatory Authorities /NACs,
 - GMP/production experts,
 - Bio-risk management experts
 - Laboratory experts.
- At least 50% of the GCC-CWG members must be present during the monthly teleconference to meet a quorum
- Members of the GCC-CWG will be appointed to serve for a period of 3 years with the possibility of one renewal
- Members of the GCC-CWG must respect the impartiality and independence required by WHO. In performing their work, GCC-CWG members may not seek or accept instructions from any Government or authority external to the WHO. GCC-CWG members must be free of any conflict of interest, real, potential or apparent, including:
 - Any financial relationship with a PEF as an employee or an auditor
 - Membership of the containment advisory group (CAG)
- Proposed members will be required to complete a declaration of interest form and their appointment, or continuation of their appointment, will be subject to the evaluation of completed forms by the WHO secretariat, to determine whether their participation will give rise to any conflict of interest, real, potential or apparent.