Poliovirus Containment Certification Scheme, 2nd edition

Draft for public consultation

CCS 2.0

World Health Organization

Poliovirus Containment Certification Scheme, second edition

CCS 2.0

Poliovirus Containment Certification Scheme (CCS) to support the certification of facilities against the biorisk management requirements for the retention of polioviruses

World Health Organization

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the CCS Revision Working Group. Comments MUST be received by 27 January 2025 and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Poliovirus Containment Team (CNT). Comments may also be submitted electronically to the Responsible Officer: Mr Derek EHRHARDT at the following email address: ehrhardtd@who.int

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ABBREVIATIONS AND ACRONYMS

CAG	Poliovirus Containment Advisory Group
CC	Certificate of containment
CCS	Poliovirus Containment Certification Scheme
CCS 2.0	Poliovirus Containment Certification Scheme 2.0
CP	Certificate of participation
GAPIV	Global Action Plan IV
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GCC–CWG	Containment Work Group of the GCC
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
ICC-NC	Nonconformity under an ICC
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NAC	National authority for containment
NC	Nonconformity
NC1	Category 1 (major) nonconformity
NC2	Category 2 (minor) nonconformity
OHSAS	Occupational Health and Safety Assessment Series
OPV	Oral poliovirus vaccine
PEF	Poliovirus-essential facility
VDPV	Vaccine-derived poliovirus
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

DEFINITIONS

Audit: The systematic, independent[1] and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. In the context of the Poliovirus Containment Certification Scheme, the term "audit" may be applied to a gap assessment and/ or interim certificate of containment/certificate of containment assessments.

Audit plan: The audit plan is made up of a timetable and schedule of the events or activities performed by an audit team during an onsite audit over a set number of days determined to be appropriate for a facility compliance verification process.

Biorisk: Risk relating to biosafety and biosecurity where the principal hazard is a biological agent (in the case of this document, poliovirus).

Biorisk management system: The organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining an organization's biorisk management policy.

Biosafety: The containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity: Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release.

Breach: An occurrence or event that results in a facility-associated release of poliovirus subject to the containment requirements of GAPIV due to the loss or failure in poliovirus containment.

Certificate of containment (CC): A certificate that can only be awarded to poliovirus-essential facilities that hold a valid certificate of participation or interim certificate of containment. A CC indicates that the poliovirus-essential facility has achieved full compliance with the biorisk management standard as described in Annex 1 of GAPIV, as independently verified by the national authority for containment (NAC) of the hosting country, in consultation with the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) and its working group (GCC–CWG). A GCC-endorsed CC bears the signature of the GCC and a unique CC number.

Certificate of containment, interim (ICC): A certificate that can only be awarded to facilities that hold a valid certificate of participation. An ICC indicates that the poliovirus-essential facility does not meet all the requirements of GAPIV but has identified the outstanding gaps in compliance and has interim adequate alternative measures in place. An ICC is awarded to a poliovirus-essential facility by the national authority for containment of its hosting country, in consultation with the GCC–CWG. A GCC-endorsed ICC bears the signature of the GCC and a unique ICC number.

Certificate of participation (CP): A certificate that indicates that NAC of the hosting country, in consultation with the GCC has recognized the facility as a suitable candidate to become a poliovirus-essential facility. The GCC–CWG assesses the information provided by the facility and NAC in the CP application form and relevant supporting documentation. A CP formalizes the eligibility of the facility to engage in the CCS process. A GCC-endorsed CP bears the signature of the GCC and a unique CP number.

Certification: The systematic, documented process to ensure systems perform in

[1] Independent from the organization being audited.

accordance with available certification standards or applicable validation guidance.

Containment: The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

Containment Audit Proposal: A Containment Audit Proposal comprises a timeline of audit activities (including monitoring and reporting for an ICC and progression to a CC, where applicable) and a description of the audit team.

Containment Working Group (GCC–CWG): The GCC–CWG is a group of independent professionals established following GCC recommendation[2] to advise the GCC on the approval of certification of poliovirus-essential facilities. The GCC–CWG is responsible for the day-to-day activities[3] associated with the endorsement of NACs' poliovirus containment certification efforts.

Corrective and Preventive Action Plan (CAPA): The actions or measures implemented aimed at ensuring compliance with requirements described in a standard such as GAPIV. Corrective actions are identified following the determination of root-causes of a nonconformity and include preventive measures to ensure nonconformity does not recur.

Facility: Any site (e.g. laboratory, repository, vaccine production unit or other) owned or operated by any level of government, academic institution, corporation, company, partnership, society, association, firm, sole proprietorship or other legal entity

Facility, poliovirus-essential (PEF): A facility designated by the ministry of health or another designated national body or authority (e.g. ministry of defense) as serving critical national or international functions that involve the handling and/or storage of needed poliovirus materials under conditions set out in the biorisk management standard (Annex 1) of GAPIV.

Gap assessment: A technique used to determine the steps needed to move from an existing state to a desired future state. A gap assessment performed by members of the audit team, for example, allows a facility to have a better understanding of its existing situation and of the steps it should undertake to achieve full conformity to GAPIV requirements.

Global Commission for the Certification of the Eradication of Poliomyelitis (GCC):

The GCC defines the parameters and processes by which polio eradication will be certified, in particular, considering a global risk assessment, surveillance quality, inaccessible populations, poliovirus epidemiology, and containment of WPV and VDPV. In addition, the GCC will receive and review the following information sources for certification of eradication of WPV1 and WPV3: reports from Regional Commissions for Certification of the Eradication of Poliomyelitis, including updates on any event or outbreak since each Region's certification that may have affected a Region's polio free status, in view of the time since certification in some Regions; additional letters of verification from Member States on the last known WPV1 and WPV3 detection in their country; global summary of poliovirus laboratory data and a report on the status of safe and secure poliovirus containment from the GCC Containment Working Group.

Guidelines: Principles or criteria guiding or directing action.

Incident: An occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm.

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[2] 14th GCC Meeting, Bali, Indonesia, 20-21 Sept 2015. See https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/

[3] 15th GCC meeting, Colombo, Sri Lanka, Dec 2016. See https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/

Initial visit: A preliminary site visit of a facility by members of the audit team to evaluate the readiness of an organization before a full audit. It also provides an opportunity for the audit team to develop the Audit Plan and identify focus areas for the initial certification audit.

Interim certificate of containment (ICC):
see Certificate of containment, interim.

Nonconformity under an ICC (ICC-NC):
Nonconformity that cannot be closed within 90 days of agreement on a Corrective Action Plan due to the need for major structural work or similar operational challenges that prevent timely closure, thus preventing the issuance of a certificate of containment (CC). All outstanding ICC-NCs must be closed prior to the issuance of a certificate of containment. By definition, all ICC-NCs will be major nonconformities NC1s since they represent an absence of one or more required system elements.

National authority for containment (NAC): The national authority responsible for ensuring poliovirus containment certification of domestic facilities. NACs are nominated by the ministry of health or other designated national authorities.

Nonconformity (NC): Non-fulfilment of a requirement; the occurrence of a condition that does not conform to the specifications of the prescribed standard.

Organization: The legal entity responsible for the management of the facility, such as a university, private company or government agency.

Poliovirus-essential facility (PEF): see Facility, poliovirus-essential.

Root cause analysis: A determination of the source or cause of nonconformities with requirements described in a standard such as GAPIV. A variety of approaches, tools or techniques may be used to identify the causes or problems associated with the specific nonconformity.

Safeguards, facility: Containment precautions and stipulations designed to minimize the facility-associated poliovirus risk of exposing or infecting operators or the surrounding populations and the release of untreated effluent.

Safeguards, immunization coverage: The population poliovirus immunization coverage consistent with minimizing the consequence of a poliovirus release from a poliovirus-essential containment facility.

Safeguards, environmental: The environmental, sanitation and hygiene conditions (good personal, domestic, and environmental hygiene standards; closed sewage systems with secondary or greater effluent treatment) that minimize the risk of reestablishing the circulation of highly transmissible poliovirus in the event of a reintroduction.

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

1. Introduction

This document, Poliovirus Containment Certification Scheme, second edition (CCS 2.0), defines the recommended mechanism for containment certification associated with global confirmation of poliovirus containment within poliovirus-essential facilities (PEFs). The Poliovirus Containment Certification Scheme (CCS) described here supplements the WHO Global Action Plan for Poliovirus Containment, fourth edition, 2022 (GAPIV). This version of CCS supersedes the previous version (2017) and includes stakeholder experience and lessons learned from the implementation of poliovirus containment certification mechanisms and processes as described in the previous edition of CCS. Feedback on the implementation of the CCS may be raised during the meetings of poliovirus containment national and global oversight bodies and transmitted to the GCC. GAPIV requires that facility safeguards, immunization coverage safeguards and environmental safeguards be set in place to effectively control and minimize the risks of facility-associated poliovirus release after eradication. While the implementation and maintenance of facility safeguards are managed by the PEFs, the compliance with immunization coverage and environmental safeguards are the responsibility of the facility-hosting countries. As a result, close coordination between the facilities and hosting countries is key to achieving the objective of retaining needed poliovirus materials in a limited number of PEFs worldwide.

The poliovirus containment certification process described in this CCS document begins with the facility-hosting country demonstrating that the required immunization coverage safeguards and environmental safeguards described in GAPIV are in place. While the appropriate implementation of immunization coverage safeguards and environmental safeguards and its reporting to the GCC–CWG is expected at the time of CP, ICC and CC application submission, the CCS addresses only the assessment of facility safeguards.

This document describes the containment certification requirements as applicable to the biorisk management standard for poliovirus-essential facilities retaining polioviruses described in GAPIV. Laboratories, repositories and polio vaccine production facilities handling or storing poliovirus materials must minimize the risk of poliovirus reintroduction into the community.

1.1 PURPOSE

The aim of the CCS is to ensure a globally harmonized approach for the certification of PEFs against the implementation of facility safeguards described in GAPIV. The CCS provides guidance to stakeholders in terms of expectations, mechanisms, roles, responsibilities and timelines associated with the certification process. The successful adoption of this mechanism by countries hosting PEFs will result in the ability to award a containment certificate endorsed by the GCC as established for this purpose.

Failure to observe the requirements set out in this document could lead to challenges in the ability of the GCC to report a globally harmonized approach to the certification of poliovirus containment. Although adherence to the CCS is voluntary, all countries hosting PEFs are strongly encouraged to participate so they effectively contribute to the mechanism that allows the GCC to assure the global community that GAPIV is being implemented adequately and consistently around the world. While countries may elect to adopt alternative mechanisms, these may not meet the CCS's requirements. Any certificates issued under such arrangements will not receive GCC endorsement.

With the 2018 World Health Assembly resolution 'Poliomyelitis – containment of polioviruses', WHO member states universally committed to accelerate poliovirus containment action, including through the establishment of NACs and the engagement of PEFs in the CCS.

The ability to demonstrate that a NAC has adopted an agreed and approved mechanism for containment certification as per CCS may help stakeholders to assess the validity of national certificates. A laboratory facility that holds a GCC-endorsed and countersigned certificate may subsequently be more likely to maintain international collaborations. Similarly, a GCC-endorsed and countersigned certificate may facilitate the placing of polio vaccine manufacturing and related products on the market in certain countries.

1.2 MAINTENANCE

WHO is responsible for developing and maintaining the CCS and publishing this document.

1.3 BACKGROUND

GAPIV was developed by WHO to provide a comprehensive and risk-based framework to ensure organizations that handle and/or retain poliovirus do so with due regard for biorisk management. A key GAPIV principle is that only those facilities that serve critical functions would be expected to continue to operate, thereby reducing the number of PEFs worldwide and minimizing the risk of a facility-associated release of polioviruses. Such facilities may include those that manage:

- Salk-inactivated polio vaccine and Sabin-inactivated polio vaccine production;
- the production and storage of stockpiles of oral poliomyelitis vaccines;
- vaccine quality control;
- diagnostic reagent production involving poliovirus;
- poliovirus diagnostic and reference functions; and
- crucial poliovirus-related research.

The Biorisk Management Standard for Poliovirus-essential Facilities retaining WPV/VDPV and OPV/Sabin polioviruses described in GAPIV consists of 14 elements and sub-elements and is aligned to the principles of biorisk management outlined in the WHO Laboratory Biosafety Manual, Fourth Edition, 2020 and relevant international standards. The 14 elements address all areas associated with the design, operation and management of the facilities that will be responsible for ensuring that the risk of unintentional or malicious release of poliovirus is minimized.

This document outlines key roles, responsibilities and associated mechanisms for stakeholders relating to the containment certification scheme. A critical aspect of maintaining both biorisk management controls and associated confidence in these controls will be the ongoing need to certify that poliovirus containment measures are being effectively implemented and maintained. The assessment and approval mechanisms relating to containment also form a crucial element of the certification of poliovirus eradication.

A fundamental principle of GAPIV and the CCS is that the responsibility for the design and implementation of adequate and appropriate oversight measures relating to individual PEFs and their alignment with local conditions (including national regulations) rests with the NACs. A number of templates relating to the CCS are available via the Global Polio Eradication Initiative (GPEI) website to support the implementation of the certification scheme. To ensure global harmonization of the containment certification process, NACs must submit application packages to the GCC–CWG using the provided forms. These forms may be adapted to local situations e.g., use of NAC logo, other sections, etc., however the information requested must remain part of the adapted forms.

1.4 CCS OBJECTIVES

The objectives of the CCS are to:

1. identify and define the roles and responsibilities of the stakeholders who will develop, implement and monitor the CCS, including the provision of required oversight, transparency and consistency of the approach;
2. specify the mechanisms required for oversight at the international and national levels, ensuring robust, transparent and equitable means are applied for containment certification across sectors and geographies;
3. describe the relevant oversight mechanisms to assure that GAPIV controls have been appropriately identified, implemented and monitored in accordance with poliovirus containment certification timelines; and
4. define and execute appropriate recording and reporting mechanisms, ensuring confidence in the CCS and its ability to provide the required level of assurance to stakeholders and the global community.

The CCS is similar to that used in other risk-based management system certification schemes (e.g., ISO 45001:2018 Occupational Health and Safety Assessment Series – Requirements with guidance for use[4]) aiming to provide an assurance of compliance against critical aspects of poliovirus containment, while also ensuring organizations focus on the critical areas that matter most in driving continual improvement. The structure and nature of GAPIV and the associated CCS are therefore designed to enable PEFs to demonstrate strict poliovirus-specific control measures, while improving performance through the consistent adoption of evidence-based practices in biorisk management.

Although ownership for oversight and containment certification of PEFs rests with designated NACs in collaboration with the GCC–CWG, the scheme will be delivered through engagement with a variety of stakeholders, including ministries of health (and other relevant government entities) and WHO.

1.5 NATURE AND TYPE OF FACILITIES ADDRESSED BY THE CCS

The facility types and activities covered by the CCS are:

1. polio vaccine production facilities, including associated quality-control laboratories, animal houses, filling lines, packaging areas, vaccine/ seed storage areas and other relevant spaces;
2. national control laboratories involved in the control and release of poliomyelitis vaccines;
3. facilities that conduct basic and biomedical research and clinical trials with polioviruses, and those that may use polio material for quality control, testing and/or validation purposes, and those producing diagnostic kits and/or materials for reference or other forms of testing; and
4. facilities housing repositories, culture collections and other specialized and dedicated

[4] International Organization for Standardization (ISO). Occupational health and safety management systems — Requirements with guidance for use. 45001:2018. Geneva: ISO; 2018

forms of storage of polioviruses, including vaccine stockpiles that must be kept for several years, even beyond expiry/ withdrawal dates.

Depending on the risk, nature and scale of processes and other relevant factors associated with each of the above, the audit duration, audit team profile, competence requirements and other factors will be defined and addressed by the NAC with endorsement from the GCC–CWG as part of the containment certification process.

1.6 ROLES AND RESPONSIBILITIES

Oversight mechanisms have been set in place to support safe and secure poliovirus containment within PEFs.

The stakeholders key to the success of the containment certification process are the:

- poliovirus-essential facility (PEF)
- national authority for containment (NAC)
- Global Commission for the Certification of the Eradication of Poliomyelitis (GCC)
  - GCC - Containment Working Group (GCC–CWG)
- World Health Organization (WHO).

The following sections describe these mechanisms and how they relate to the various responsible stakeholders.

Poliovirus-essential facility

The PEF:

1. establishes, implements and maintains a biorisk management system aligned with the requirements set out in GAPIV;
2. provides relevant stakeholders (NAC and audit team members) with access to all information and facilities relevant to containment certification activities;
3. achieves and maintains containment certification and operates within the terms of the certificate throughout the certification cycle; and reports to the NAC and other relevant parties any accident, incident, or event, change to processes, change in facility, programme of work, or other issue that could jeopardize the status of a certificate under the CCS.

National authority for containment[5]

The NAC:

1. verifies that the required facility-, immunization coverage- and environmental-safeguards described in GAPIV are met and reports on these safeguards to the GCC–CWG as part of certificate applications;
2. establishes national mechanisms aligned with the CCS to ensure PEFs are appropriately assessed and comply with GAPIV requirements;
3. reviews and processes applications for containment certification in consultation with the GCC–CWG, ensuring only relevant facilities enter the containment certification

[5] For reasons of potential conflict of interest, the NAC cannot be the national reference laboratory that functions as a facility dedicated to such activities as surveillance. Under some circumstances the national reference laboratory may also apply to become a PEF.

process;

4. conducts containment certification activities so as to provide adequate assurance that the requirements set out in GAPIV and the CCS are effectively implemented and maintained;

5. establishes and maintains effective procedures to address relevant aspects of the containment certification cycle, including:
   - application and acceptance
   - contract/agreement or another modality with the PEF applying for a certificate of containment (CC) or interim certificate of containment (ICC)
   - planning of audits
   - review of applications and other documents
   - initial and periodic audits
   - resolution of findings
   - certificate issuance
   - certificate maintenance
   - certificate renewal;

6. establishes and maintains effective procedures to verify that internal processes function appropriately, including:
   - definition of roles, responsibilities and authorities
   - control of documents and records
   - confirmation of auditor competence, qualification and team composition
   - definition of audit scope and associated costs
   - reporting and follow-up of findings
   - use of certificates and logos
   - conduct of internal audit and review
   - confirmation of independence, impartiality and confidentiality

7. provides relevant parties (PEFs, audit team members, GCC, GCC–CWG, and WHO) with appropriate access to pertinent information required for containment certification activities;

8. provides relevant parties (e.g. GCC–CWG) with access to pertinent information demonstrating that immunization coverage and environmental safeguard requirements are appropriately met, with consideration for facility confidentiality requirements;

9. adheres to the principles and practices as set out in ISO/IEC 17021-1:2015 (5) Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements;

10. investigates, compiles and analyses all data from the PEF on all reported incidents and breaches (see definitions) involving poliovirus and reports to the GCC–CWG;

11. Keeps GCC–CWG informed of pertinent information related to containment certification activities when it becomes aware of them, including but not limited to breaches, accidents which may have resulted in exposure to poliovirus, and change of programme of work; and

12. issues, suspends or revokes certificates of containment, in consultation with the GCC–CWG.

Global Commission for the Certification of the Eradication of Poliomyelitis – Containment Working Group

The GCC – Containment Working Group (GCC–CWG), established following GCC recommendation[6], is responsible for the day-to-day activities associated with containment certification, in support of the GCC. The GCC–CWG:

1. reviews applications to ensure that a designated PEF is eligible to join the certification process;
2. endorses the process to award containment certificates;
3. reviews and endorses all materials submitted by the PEF for the purpose of entry into and progress through the CCS based upon information supplied through the GCC-endorsed process (following the CCS);
4. reviews and endorses Containment Audit Proposals and auditor/audit team applications based upon information supplied by the NACs;
5. endorses the issuance of containment certificates (certificates of participation, interim certificates of containment and certificates of containment) submitted following the CCS process.

Global Commission for the Certification of the Eradication of Poliomyelitis

The GCC:

1. countersigns containment certificates endorsed by the GCC–CWG; and
2. acts as a global oversight body and confirms the global containment of polioviruses.

World Health Organization

WHO:

1. develops, maintains and revises the CCS as necessary;
2. provides secretariat services in support of the GCC–CWG and of the GCC, including the recruitment of new members;
3. provides coordination, implementation support, technical assistance and expert advice regarding the CCS to countries, NACs, GCC, and the GCC–CWG;
4. ensure technical guidance is available to all stakeholders and the global community; and
5. addresses feedback relating to the CCS.

1.7 DELEGATION OF ACTIVITIES

Conditions to outsource auditing and related containment certification activities to a third party should be consistent with relevant sections of International Organization for Standardization (ISO) 17011 (6)/ISO 17021-1 (5), and be subject to formal contracting arrangements, with responsibility for relevant activities remaining with the NAC. Under no circumstances will the issuance of a certificate under the CCS be permissible other than via the NAC of the country hosting the PEF, in consultation with the GCC.

[6] Report of the 15th GCC meeting, Colombo, Sri Lanka, Dec 2016

2. Containment certification process

GAPIV requires PEFs handling and/or storing polioviruses to be located in countries that have demonstrated the appropriate implementation of required immunization coverage and environmental safeguards as described in GAPIV, and ultimately to achieve and maintain a CC. However, it is recognized that PEFs may require time to fully implement GAPIV requirements or cease work involving poliovirus materials to a defined timescale.

To manage the practical challenges associated with facility achievement of full compliance with GAPIV, CCS includes a sequential process of moving through the containment process (e.g., CP to ICC to CC) to achieve full compliance with GAPIV. Although not equivalent to a full CC, the CP/ICC form part of a planned transition arrangement, allowing a high degree of control to be exercised while facilities work toward full conformity. While some facilities may decide not to move forward from the CP or ICC stage (e.g., decide to destroy or transfer their poliovirus rather than achieve a CC), each step provides a progressive adherence to GAPIV requirements that allows time for facilities to make the necessary adjustments.

The process for containment certification against GAPIV requirements is described below. Records of activities and documentation related to the containment certification process for each facility should be retained for at least six years.

The issuance of a CP is a prerequisite for all facilities entering the CCS process. Going forward, any CP application is expected to be accompanied by a Containment Audit Proposal for an ICC or a CC audit. The processes for the issuance of an ICC and a CC are similar, in that both require a Containment Audit Proposal before the audit is conducted (full scope or reduced scope), regardless of previous certificates held and both have the same requirements of an application.

All applications and attached documentation must be submitted to the GCC–CWG in English.

The processes for the issuance of the three certificate types and relevant submissions are described below.

2.1 CERTIFICATE OF PARTICIPATION

The issuance of a CP initiates the certification process and formally engages a facility designated as serving critical functions in the mechanism to achieve an ICC/CC or cease activity to a defined timescale. A CP is issued to facilities by their respective NAC following endorsement from the GCC in consultation with the GCC–CWG, to demonstrate that they have been accepted as eligible applicants to enter the CCS process.

Recognizing the approaching end-2026 deadline for the obtention of a CC or ICC with a clear endpoint for obtaining a CC by facilities retaining poliovirus materials[7], going forward all new CP applications must include a Containment Audit Proposal (see section 2.2) for an ICC or CC (see section 2.2 for details). The Containment Audit Proposal timeline should include a timeline of audit activities which is aligned with the facility time-bound action plan and clearly indicates how the facility intends to complete all required activities to achieve a CC or an ICC with a clear endpoint to obtain a CC agreed with the GCC–CWG by end-2026[8]. 'Endpoint' refers to the audit at which the closure of all NCs is verified per the NAC-approved and GCC–CWG-endorsed corrective action plan. Facilities which have previously been awarded a CP and which have not yet progressed to an ICC or CC must submit their Containment Audit Proposal in a timely manner so as to meet the end-2026 deadline. In such instances where a PEF will not achieve a CC by end-2026, the PEF must submit a request to the GCC–CWG via the NAC to achieve only an ICC by the deadline, demonstrating the legitimacy of such a request and detailing the extenuating circumstances.

On condition that the facility-hosting country has presented evidence of compliance with immunization coverage and environmental safeguards, a CP is issued provided the following conditions are met:

1. The facility seeking certification under the CCS is deemed suitable by the NAC as a candidate, and is considered to have accepted the need to comply with GAPIV requirements and obtain an ICC/CC. In addition, the applicant PEF is considered capable of ultimately meeting ICC/CC requirements, including having access to adequate resources. Alternatively, the facility may plan to cease work with poliovirus to a defined timescale approved by the NAC and endorsed by the GCC in consultation with the GCC–CWG; in such cases it is agreed that the CP will subsequently be revoked, and no ICC/CC will be issued. The agreed-upon timeline for work cessation will be indicated in the CP application.
2. An application for a CP is submitted by the candidate facility to the NAC (see the Certificate of Participation Application Form), detailing:
    a. the certificate ultimately being sought (CP/ ICC/CC);
    b. the need/rationale for retaining poliovirus materials subject to containment through the CP phase, including the current containment conditions in the facility and whether the retained poliovirus materials will subsequently be:
        i. destroyed and, if so, when and by what means
        ii. transferred to containment within an alternative PEF
        iii. held in secure storage and, if so, where and under what conditions
        iv. manipulated as part of an ongoing programme of work
        v. used in conjunction with other activities deemed appropriate by the NAC in consultation with the GCC–CWG; and
    c. an outline of a time-bound action plan specifying the proposed measures to be undertaken by the facility to achieve ICC/CC status or cease work with poliovirus.

3. A Containment Audit Proposal detailing the following is supplied by the NAC as part of the application (see section 2.2 for a detailed description of the Containment Audit Proposal):
    a. the proposed audit team, and
    b. a timeline of audit activities which is aligned with the PEF's time-bound action plan for achieving a CC or ICC with clear endpoint for to achieving a CC by

[7] See the Containment page of the GPEI website for latest GCC recommendations concerning which poliovirus strains are subject to containment requirements: Containment – GPEI (polioeradication.org)
[8] See the Containment page of the GPEI website for latest GCC recommendations concerning which poliovirus strains are subject to containment requirements: Containment – GPEI (polioeradication.org)

end 2026[9] or cessation of work before then.

4. The NAC has reviewed the application to ensure the facility is potentially capable of meeting the criteria for a PEF in relation to GAPIV, completed the additional parts of the applications and included the requested evidence or documentation before submission to the GCC–CWG. The NAC then submits satisfactory applications and Containment Audit Proposals to the GCC–CWG for endorsement, including an overview of any proposed evaluation and monitoring activities, designed to ensure work relating to the CP will be conducted appropriately.

Following transmission of the CP application and Containment Audit Proposal to the GCC–CWG by the NAC, they will undergo a review process as follows:

1. The GCC–CWG reviews the facility hosting country's implementation of immunization coverage and environmental safeguards.
2. The GCC–CWG reviews the CP application and Containment Audit Proposal at their monthly virtual (for Containment Audit Proposals) or quarterly in-person (for certificate applications and Containment Audit Proposals) meetings. The GCC–CWG chooses whether to endorse the issuance of the certificate or Containment Audit Proposal. Should the application or Containment Audit Proposal be considered unsatisfactory, additional information may be sought or a recommendation may be made to withhold/delay the issuance of a CP, leading to a potential suspension of work with poliovirus, the destruction of materials or the need to transfer them to a facility providing suitable containment (holding an endorsed CCS certificate for the intended use, i.e. storage, handling, etc.). Provided no significant objections are raised, the applicant PEF can enter the CCS process through the issuance of a GCC-endorsed CP by the NAC. If the application is not endorsed by the GCC–CWG, more information may be requested and the applicant can choose to resubmit, provided additional information is made available via the NAC that clarifies any outstanding questions on the application from the GCC–CWG.
3. The NAC is encouraged to communicate the outcome of the application to the candidate facility within ten working days of the date of receipt of the recommendation or as determined by the NAC.
4. A CP will state the conditions for containment of poliovirus in the period prior to the issuance of an ICC/CC, which may include:
    a. expected timelines for achieving an ICC/CC, with consideration for the end-2026 deadline for achieving a CC or an ICC with a clear endpoint for achieving a CC agreed with the GCC–CWG; and
    b. an ability to continue work under stipulated conditions, together with any specific restrictions.
5. The validity of a CP is time-bound and limited to a maximum period of one year or as determined by the GCC–CWG, during which CP-holding facilities are expected to be awarded an ICC/CC or cease work with poliovirus. If there is a delay in PEF progression to an ICC which is caused by the NAC, the CP will be extended automatically.

A CP awarded by the NAC without the GCC's endorsement will fail to meet CCS requirements and will not be regarded as a GCC-endorsed certificate under the scheme.

2.2 CONTAINMENT AUDIT PROPOSAL FOR ICC OR CC

In advance of initiating any ICC or CC audit activity, NACs should submit a Containment Audit Proposal for ICC or CC for each facility in the country to the GCC–CWG for approval. Submission of this plan ensures that the GCC–CWG reviews and endorses the planned audit

[9] See the Containment page of the GPEI website for latest GCC recommendations concerning which poliovirus strains are subject to containment requirements: Containment – GPEI (polioeradication.org)

activities and audit team so as not to delay any issuance of a certificate. This plan should be submitted together with any CP application for the ICC initial audit and ahead of CC initial and recertification audits, and consists of:

1. Timeline for the conduct of the different ICC audit and related activities (e.g., initiation and planning; gap assessment and initial visit; initial audit, reporting and follow-up; review and approval; monitoring; cessation of work, if applicable).

2. Auditors and audit team composition – documentation for proposed national auditors by NACs should include a list of proposed auditors along with their detailed qualifications and Audit Team Membership Application Forms for any candidates not previously endorsed by the GCC–CWG. Audit Team Membership Application forms should be completed with particular attention given to previous audit experience (page 5) including highlighting the relevant experience with the type of facility to be audited (e.g., vaccine manufacturing, research, storage facility, etc.). Other audit team members (e.g., technical experts) should submit the same documentation. The GCC–CWG will especially look into previous audit experience of the proposed auditors in relevant disciplines. Consideration will be given both to the competencies of individual audit team members and to that of the team as a whole.

A Containment Audit Proposal must be endorsed by the GCC–CWG for each facility in the country pursuing an ICC or CC before the start of any audit activities. A Containment Audit Proposal must be submitted prior to the start of audit activities for an ICC or CC initial audit and for a CC recertification audit. Periodic audits and verification of the closure of NCs generally do not require Containment Audit Proposals; however, these must be completed by GCC–CWG-endorsed auditors, and ideally by the same auditors who conducted the initial audit. If there is a change in the audit team from the initial audit, a list of auditors who will conduct the periodic audit or verification of closure of NCs must be submitted to the GCC–CWG for endorsement prior to the start of any audit activities. Any ICC/CC application that is submitted without GCC–CWG endorsement of the Containment Audit Proposal before the audit was performed may be more likely to require additional information from the NAC and/or PEF, leading to potential delays in GCC–CWG endorsement and possibly the need for a facility re-audit.

2.3 INTERIM CERTIFICATE OF CONTAINMENT

An ICC will be issued to a facility that does not meet all the requirements of GAPIV but has identified the outstanding gaps in conformity (nonconformities) and implemented adequate alternative measures for nonconformities which cannot be resolved within 90 days due to the need for major structural work or other similar reasons (ICC-NCs). These measures must have been approved by the NAC prior to the submission of an ICC application and endorsed by the GCC–CWG. Adequate alternative measures must be in place for work with poliovirus to continue while action is taken to address the need for full conformity or to cease work. This may include facilities that require temporary approval while alternative arrangements for more permanent conditions are finalized.

Although an ICC does not imply full conformity to GAPIV requirements, it is emphasized that this in no way indicates an increased tolerance for risk relating to facilities storing or handling poliovirus. The measures relating to the issuance of these certificates will be controlled through the CCS and be of limited duration and scope as described in this document.

Prior to the start of ICC audit activities, a Containment Audit Proposal for ICC audit must be submitted to the GCC–CWG via the NAC and endorsed by the GCC–CWG.

An ICC is issued provided the following conditions are met:

Initiation and planning

1. The NAC should engage the PEF in the ICC process through the establishment of a contract or agreement with the facility. The contract/agreement between the PEF and NAC will address at a minimum:
    a. the management of confidentiality, including with whom documents and other data can be shared and how such information may be released to other parties if necessary;
    b. the management of any potential conflicts of interest;
    c. fees and charges, if applicable;
    d. how and by whom disputes will be managed;
    e. requirements for the translation of documents and the presence of translators on-site during the assessment;
    f. a guarantee that audit team access to all rooms of the containment area will be granted; and
    g. the health, safety and welfare of the audit team throughout the containment certification process (a declaration may be included to that effect).
2. Once the contract/agreement is in effect, the NAC should start planning for the initial full-scope ICC audit against Annex 1 of GAPIV. The purpose of the initial audit is to ensure that all proposed controls in place during the period of the ICC are adequate and to identify any areas where nonconformities (NCs) may exist. At this stage, a CP-holding facility may arrange for an initial visit and/or gap assessment to ensure that all relevant containment-related issues are clearly understood by both the NAC and PEF, and that relevant measures (both facility-related and organizational) are in a high state of readiness. The audit team composition and duration for a gap assessment may be less than that required for a full certification audit, reflecting the nature of the activity. Although neither an initial visit nor a gap assessment is mandatory, consideration for the need and advantage to perform these activities should be given to instances where an unsatisfactory certification visit could result in major difficulties, including the potential need for a repeat visit by the audit team or could result in an extensive list of NCs. Neither an initial visit nor a gap assessment can be used as the basis for the issuance of an ICC or CC under the CCS.
3. If NCs are identified before or during the initial audit that cannot be fully addressed prior to the issuance of the ICC due to the need for major structural work or similar operational challenges (e.g., the need to install a handwashing sink), these are ICC-NCs and a detailed, documented, independently peer-reviewed risk assessment will be prepared. The risk assessment will be reviewed and endorsed by the NAC as part of the process to recommend the issuance of the ICC[10].

Initial audit, reporting and follow-up

1. A full-scope initial audit, which must be planned and conducted in line with the requirements set out in this document, must be completed to qualify for ICC status[11]. Within 10-20 days following the audit (or as determined by the NAC), an audit report detailing any NCs should be produced and submitted to the PEF (see section 4.7). During an ICC audit, standard Category 1 NC (NC1) and Category 2 NC (NC2) findings can be issued, as well as ICC-NCs. Audit reports should be completed in a way that provides assurance to national and global oversight bodies that all sub-elements of GAPIV have been audited, including elements in which no nonconformities have been identified (see Audit Report Template).
2. Within 40 days of receipt of the report, or as determined by the NAC, the PEF is

[10] Should the NAC have the required expertise and other resources, it may assume the role of the independent reviewer, if there is no risk of conflict of interest and this is deemed appropriate.
[11] Detailed descriptions relating to audit teams, plans, schedules and on-site activities are provided in sections 3 and 4 below.

encouraged to develop a Corrective and Preventive Action Plan detailing how and by when all identified NCs will be closed using the Audit Findings and Corrective and Preventive Action Plan form. If ICC-NCs are identified, a detailed, documented, independently peer-reviewed risk assessment must be prepared by the PEF and adequate alternative measures implemented. The risk assessment will be approved by the team leader and NAC as part of the process to recommend the issuance of the ICC (see section 4.6, *Nonconformities under an ICC (ICC-NC)*).

3. Once the facility has completed the Audit Findings and Corrective and Preventive Action Plan, the plan will be reviewed by the audit team leader for completeness to ensure that the actions proposed are appropriate, sufficient and timely. Any additional actions considered necessary are expected to be communicated to the facility within 20 working days, and the responses received within a further 20 working days, or as determined by the NAC.

Review and approval

1. Upon satisfactory completion of the ICC initial audit and approval of the Corrective and Preventive Action Plan by the lead auditor and the NAC (including the NAC's review of the overall conduct of the audit), the NAC submits all relevant documents to the GCC–CWG. Submitted documentation will include the initial full-scope ICC Audit Report, incorporating the list of identified NCs, and the Audit Findings and Corrective and Preventive Action Plan, together with risk assessments and any other supporting documents indicated on the application form (e.g. Audit Plan, Evidence of Immunization Coverage Safeguards, Evidence of Environmental Safeguards, etc.), and a recommendation regarding the award of the ICC. All applications for a containment certificate (CP, ICC and CC) must include the most up-to-date available evidence of immunization coverage safeguards and environmental safeguards as described in GAPIV, provided by the NAC.

2. The ICC application will first go to the GCC–CWG Secretariat, where it will be reviewed for completeness. Should the GCC–CWG Secretariat request additional information prior to GCC–CWG review, the NAC is requested to respond as soon as possible, variable based upon the date of the next GCC–CWG meeting, so as not to delay application review. When the Secretariat deems the application complete, it will be shared with the GCC–CWG and reviewed within 120 days.

3. The GCC–CWG will then provide feedback, via the GCC–CWG Secretariat, to the NAC on the status of the ICC application. Should the submission be considered satisfactory, the GCC will endorse the issuance of the certificate by the NAC to the facility. Should the submission be considered unsatisfactory due to nonconformity with the CCS and/or GAPIV, a request for additional information will be sent to the NAC or a recommendation may be made to withhold/delay the issuance of the ICC, potentially leading to the recommendation/need to suspend activity, destroy materials or transfer them to a facility providing suitable containment, prior to the expiry or suspension of the CP. The NAC is requested to respond to any request for information in a timely manner so as not to delay the certification process.

4. The NAC communicates the final outcome of the GCC–CWG's recommendations on the ICC application to the PEF.

Monitoring and renewal

1. The NAC monitors progress on the agreed Corrective and Preventive Action Plan for all ICC-NCs on a quarterly basis. Any additional NCs will be monitored and closed in line with section 4 of this document. For all NCs, closure is verified by the lead auditor. A progress report or evidence of closure for all identified NCs should be submitted to the GCC–CWG alongside the periodic audit reports. Periodic audits are reduced-scope audits for which the Audit Report template should still be used. However, only the relevant GAPIV elements (based on previously identified NCs and any areas the audit team

wishes to assess) must be addressed within the audit. If the Corrective and Preventive Action Plan schedule is not adhered to, the ICC may be suspended or withdrawn, and work required to cease.

2. The duration of an ICC is time-bound and should be of the shortest possible duration with consideration for the end-2026 deadline to achieve a CC or an ICC with clear endpoint to achieve a CC agreed with the GCC–CWG. In such instances where a PEF will not achieve a CC by end-2026, the PEF must submit a request to the GCC–CWG via the NAC, demonstrating the legitimacy of such a request and detailing the extenuating circumstances.

3. The certificate is issued following the successful completion of the initial full-scope certification audit against all 14 elements specified in Annex 1 of GAPIV, followed by annual periodic audits within 12 months of the previous audit.

An ICC awarded by the NAC without the GCC's endorsement will fail to meet CCS requirements and will not be regarded as a GCC-endorsed certificate under the scheme.

2.4 CERTIFICATE OF CONTAINMENT

A CC can be issued either directly following the award of a CP or as an upgrade to an ICC[12] once the PEF presents evidence to the NAC that all GAPIV requirements have been met, submit a CC application, and receive endorsement from the GCC–CWG. Additionally, at least the lead auditor on a CC audit must have undergone GAPIV training. If the ICC is upgraded to a CC during the ICC validity, the certification cycle remains unchanged (i.e. it is upgraded to CC within an ongoing three-year cycle). A Containment Audit Proposal for CC audit must be submitted to the GCC–CWG via the NAC and endorsed by the GCC–CWG prior to the start of CC audit activities.

A CC is issued provided the following conditions are met:

1. Where a CC is sought directly from a CP, the process is the same as described for issuance of an ICC, but without the need for specific risk assessments relating to identified ICC-NCs, as open ICC-NCs are not permitted under a CC.

2. All NCs must be closed before a CC can be issued.

3. If a transition from an ICC is required, appropriate audit and verification measures will be defined by the NAC in relation to the number and nature of the NCs in place. This may require a reduced-scope audit with a smaller, more specialized team where appropriate. The NAC will present evidence to the GCC that all NCs have been satisfactorily closed and will make a recommendation as to whether to proceed to CC status. As for applications for any CCS certificate, CC applications must include the most up-to-date evidence of immunization coverage safeguards and environmental safeguards as described in GAPIV, provided by the NAC. The NACs should also demonstrate that at least the lead auditor has undergone GAPIV Training for Auditors. Two paths exist for the pursuit of a CC from an ICC:

    a. A facility awarded a GCC-countersigned ICC against GAPIV:

        i. Under condition that at least the lead auditor has undergone GAPIV Training for Auditors and that all NCs have been determined as being effectively closed during a periodic or ad hoc audit as verified on site for NC1s and ICC-NCs or by documentary evidence review for NC2s (or as determined by the NAC) and reviewed by the NAC, the NAC may submit a CC application to the GCC–CWG.

[12] All outstanding ICC-NCs must be closed prior to the issuance of a CC.

ii. Relevant documentation (Audit Report, Audit Plan, Audit Findings and Corrective Actions. Auditor Log, etc.) or evidence (of environmental and immunization coverage safeguards and of facility conformity with every GAPIV subelement) should be submitted to the GCC–CWG by the NAC as part of the CC application.

b. A facility awarded a GCC-countersigned ICC against GAPIII:

i. Under condition that at least the lead auditor has undergone GAPIV training, a full-scope audit must be conducted against GAPIV with all identified NCs closed before the application is submitted to the GCC–CWG.

ii. This full-scope audit against GAPIV may be conducted at any time e.g., at the time of the periodic audit for ICC year 1, but before the end-validity of the ICC.

4. A CC is valid for three years, part of which may encompass the upgrade of the certificate from ICC to CC where relevant.

5. A CC full-scope audit is repeated at the end of the three-year cycle that includes yearly periodic audits in which the effectiveness of implemented corrective actions for any NCs identified in the previous audit is verified, where successful completion will result in renewal of the CC for a further three years. This recertification application should be submitted using the Certificate of Containment Application Form, checking the box for "Certificate of Containment – re-certification application" in section II. *Type of application.* The Audit Report for the full-scope audit should be submitted alongside it. A CC confirms that the facility is compliant with all requirements set out in GAPIV as testified by a competent, independent team of auditors, operating within conditions specified under the CCS.

A CC awarded by the NAC without the GCC's endorsement will fail to meet CCS requirements and will not be regarded as a GCC-endorsed certificate under the scheme.

2.5 GCC-ENDORSED CERTIFICATES

GCC-endorsed certificates (CP/ICC/CC) bear the signatures of the respective NAC and the GCC, together with a unique identification number.

2.6 MODIFICATION, SUSPENSION, WITHDRAWAL, COMPLAINTS AND APPEALS

The ICC/CC may be withdrawn if the PEF fails to comply with GAPIV requirements. In such cases, the NAC should warn the facility[13] of the potential suspension (time-limited to six months or less), withdrawal (permanent revocation) or reduction in scope (modification) of the certificate. An appropriate means of communication (e.g. letter, email) should be identified to stipulate the background that has led to the potential action, together with steps to be taken to resolve the issues through further audit activity/other measures and/or to withdraw/modify the certificate of containment. The communication should also indicate the timelines and consequences of certificate withdrawal, including the potential need to transfer/destroy any poliovirus materials, suspend work, place restrictions on the transportation of materials, or other pertinent measures.

It is crucial that PEFs foster a culture of reporting of accidents and incidents involving poliovirus, both within the facility and to the NAC and other relevant parties, in order to increase transparency and accurate accounting of exposures and breaches.

[13] The communication should be addressed to the facility focal point identified on the GAPIV Containment Certification Application Form used to initiate the certification process.

Certificates may be withdrawn under conditions including but not limited to:

1. violation of the terms stipulated in the containment certification contract/agreement, including:
   - divergence from the indicated programme of work or type of polioviruses retained;
   - non-payment of fees;
   - failure to allow auditor access to relevant areas of the facility, documentation and/or relevant personnel;
   - abuse of the certificate and/or associated logos/other information;
2. major breaches of compliance with GAPIV and/or of associated containment certification requirements, including:
   - failure to identify and implement adequate alternative measures;
   - failure to update systems in light of new or changed circumstances (e.g. new processes/ equipment);
   - inability/unwillingness to address NCs in line with the requirements;
   - unauthorized use, transport or transfer of poliovirus or associated materials;
3. evidence received regarding the effectiveness of measures to ensure containment, including:
   - failure to meet applicable laws or other pertinent requirements;
   - failure to respond appropriately to emergencies or other untoward events; and
4. voluntary requests for suspension/withdrawal.

All correspondence related to suspensions or withdrawals should be recorded and retained for at least six years. Appeals can be made to the NAC, or directly to the GCC–CWG in exceptional circumstances, provided the NAC is kept fully informed of all correspondence. In such cases, appeals may be sent to the GCC–CWG Secretariat at containment@who.int. It is at the discretion of the GCC–CWG to decide whether it is appropriate to engage in communication directly with the PEF during an appeal. It is emphasized that the decision to suspend and/or revoke certificates may be taken in consultation with the GCC–CWG, but ultimately rests with the NAC.

2.7 NOTIFICATION OF CHANGES

Any change in programme of work for retention of poliovirus material, change of poliovirus material, change in facility physical requirements, or change in organization ownership or key personnel that affect the CP-, ICC- or CC-holding facility biorisk must be reported to the NAC immediately per GAPIV requirements and relayed to the GCC–CWG without delay.

3. The audit team

The knowledge, skills and aptitudes of the audit team form a critical component in ensuring the establishment of an appropriate containment certification process. This section provides the qualification criteria and a systematic framework for the development, recognition and documentation of the competence of CCS auditors performing the audits. The size and composition of the audit team will depend on the size, nature and complexity of the facility and associated organization to be audited and will comprise a minimum of two auditors.

Where NACs do not have sufficient qualified resources to deliver the containment certification process using in-country resources, the availability of international resources should be confirmed prior to the issuance of the contract/agreement and preparation of the schedule for the audit. Use of international resources should be indicated in the Containment Audit Proposal (see Section 2.2.).

NACs are responsible for the selection and oversight of their audit team, and for ensuring auditors are appropriately trained to perform CCS audits. So as not to delay certificate issuance, documentation for proposed national auditors (i.e. the Audit Team Membership Application Form) should be transmitted to the GCC–CWG for endorsement prior to the start of audit activities, either on an ad hoc basis or as part of the Containment Audit Proposal. The NAC should highlight team members' relevant work and/or auditing experience with the type of facility to be audited (e.g., vaccine manufacturer, research laboratory, storage facility, etc.).

The NAC and GCC–CWG should especially consider previous audit experience of the proposed auditors in relevant disciplines (ISO 45001, GMP, GLP, ISO 9001, ISO 17025, institutional practices, etc.).

While WHO may provide required training and other associated activities to support NACs in gaining access to appropriate individuals to carry out assessment activities, no provision under the CCS exists for WHO/GCC to conduct containment certification audits.

CCS audits require audit teams competent in several specialist areas, including but not necessarily limited to:

1. education and experience in infectious diseases including, if possible, poliovirus virology;
2. procedures applied in working with and maintaining poliovirus containment in the specific areas being assessed (e.g., research, diagnostics, vaccine production, filling, clinical trials, molecular biology, epidemiology, treatment, patient care);
3. GAPIV and related biorisk management issues addressing biosafety and biosecurity;
4. safety and security management systems, risk assessment and risk management;
5. emergency preparedness and outbreak response; and

6. engineering principles and concepts for biorisk management.

To perform an effective audit, teams will require knowledge and expertise across a variety of technical disciplines and must have the required skills and systems to conduct the audit in an evidence-based, unbiased and systematic manner. Recognizing that the requirements in GAPIV cover a wide variety of disciplines, the audit team will include sufficient capacity to address them all, although more than one discipline can be addressed by a single team member (e.g., a qualified engineer may be sufficiently knowledgeable about emergency preparedness measures).

3.1 QUALIFICATION OF AUDITORS AND TECHNICAL EXPERTS FOR GAPIV CERTIFICATION

The qualification of auditors, lead auditors and technical experts will be managed by the appropriate NAC. It is also the NAC's responsibility to ensure that both appropriate composition and competence within any audit team is attained.

This will be achieved through the development of documented procedures, ensuring all relevant aspects of the management of the audit team composition and competence have been defined and met. The NAC will document these criteria and how they are met through the appointment and utilization of individuals with the required knowledge and skills necessary to effectively perform and manage audits and containment certification tasks. Failure to demonstrate appropriate team composition may jeopardize the GCC–CWG's approval of an ICC/CC under the CCS.

3.2 AUDIT TEAM ROLES AND FUNCTIONS

The CCS is highly dependent on the competence, independence and dedication of lead auditors, auditors and technical experts, together with individuals and bodies engaged in all aspects of the application, review and approval processes. This section describes the roles and functions of audit team members. It provides qualification criteria and a systematic framework for the development, recognition and documentation of the competence of staff performing as:

- team leaders
- lead auditors
- auditors
- technical experts
- observers
- translators.

Team leader status is conferred to a qualified lead auditor who is responsible for planning, leading and reporting on the audit. An audit team may have more than one lead auditor, but only one should be appointed team leader.

Lead auditor status is conferred to an auditor who has met all the requirements for auditors as described in Section 3 and has demonstrated the ability to lead and manage all aspects of the audit/audit team during CCS audits.

Auditor status is conferred to individuals who have met all the required qualification requirements for auditors as described in Section 3 and demonstrated the ability to perform part of a CCS audit as a member of a team, according to the auditing procedures defined in this document.

Technical expert status is conferred to individuals who have the required technical

knowledge and experience to support the audit team in the specialty that they are recognized for. Such individuals could be appointed to support areas including but not limited to maintenance and engineering, management systems/auditing, relevant scientific specialisms (e.g., research) and production environments. It would normally be expected for technical experts to be available on-site during the audit. However, under exceptional circumstances (e.g., where there may be limited need for highly specialized expertise), such support/consultation may be provided remotely via telephone, email exchange, etc. In such situations, the nature of the association/collaboration/ relationship should be formally addressed in the audit team composition as part of the planning process.

Observer status is conferred to individuals who will attend audits but play no active role other than to comment on the potential appropriateness of the audit directly to the team leader or report to other nominated parties not represented at the audit itself. Under no circumstances should an observer comment upon or discuss directly with an audited organization matters pertaining to the conduct or results from the audit unless in the presence, with prior authorization and at the discretion and direction of the team leader. Examples of observers may include WHO representatives attending audits as part of any verification process, or NACs including observers for other reasons. Appropriate permissions and authorization relating to the presence of observers should be sought prior to the commencement of the audit.

Translator[14] status is conferred to individuals appointed to support an audit team in the translation of documents, data and oral communication relevant to the audit. Translators should hold a recognized qualification appropriate to the language and nature of the subject and audit being performed. In terms of participation, a translator should act in the capacity of observer unless part of the audit team and meeting qualifications of an auditor/lead auditor or technical expert. Translators should therefore engage only in activities associated with the translation of speech and written text and must not discuss issues with auditees or make statements/interpretations, other than to ensure good understanding for communication between the PEF and members of the audit team. Translators should be demonstrably independent of the organization being assessed.

3.3 AUDITOR COMPETENCIES OVERVIEW

An individual demonstrating the required qualities, skills and proficiency can qualify as an auditor, including:

- education and work experience
- auditing experience in biorisk management or a related field
- GAPIV training
- personal attributes.

The following sections describe criteria to be applied in assessing these areas.

3.4 EDUCATION AND WORK EXPERIENCE

A CCS auditor (lead auditor or auditor) should have relevant tertiary education, preferably an ordinary/first degree (e.g., BSc, BEng or equivalent) or higher degree (e.g., MSc, MD, PhD or equivalent). In addition, an auditor should show appropriate specific training/ competence (e.g., safety management system auditing), work experience in auditing ((e.g., ISO45001:2018, GMP, GLP, ISO 9001, institutional practices etc.) and other personal development activities that confer communication, technical and/or business acumen, as well as the analytical skills necessary to conduct and/or manage audits relevant to PEFs.

A CCS auditor should demonstrate appropriate knowledge of regulations, standards, guidelines, industry practices and other norms as they apply to the areas to be assessed, together with demonstrated competence in the relevant aspects of poliovirus biology and

[14] The term "translator" is used to include interpretation skills.

associated containment measures. Experience should relate to relevant position(s) in a managerial, supervisory and/or technical capacity where interactions with other members of the management team, auditees, regulators and other relevant parties are an integral aspect of the role.

All auditors should have a minimum of three years of full-time workplace experience within a microbiological laboratory (or equivalent environment), vaccine production facility or related/ similar environment relevant to poliovirus biology and containment.

The following sections describe the knowledge and experience that must be represented on each CCS audit team. If the NAC wishes to present a candidate for GCC–CWG endorsement who is believed to have equivalent education or experience to the stated requirement, a justification should be sent to the GCC–CWG Secretariat for GCC–CWG consideration at its monthly virtual or quarterly in-person meetings. Candidates must justify relevant work experience based on a combination of the following criteria:

Safety management systems

Candidates must:

a. Have formal tertiary education[15]

b. have formal qualification[16] in risk assessment and management, or safety management systems;

c. have worked in conducting or assessing risk management activities for a minimum of two years with specific reference to biological risk; and/or

d. have worked in a capacity providing audit/oversight activities associated with the conduct of relevant duties for a minimum of three years.

Biorisk management

Candidates must:

a. have formal qualifications in biorisk management (examples of formal qualifications include a master's degree, relevant certification from a recognized association or equivalent);

b. have worked in a relevant biosafety/ biosecurity position or in a role with significant responsibility for the conduct of such activities within a microbiology laboratory/production environment, for a minimum of two years; and

c. have worked in a capacity providing audit/ oversight activities associated with the conduct of relevant duties for a minimum of three years.

Research, diagnostics, production environments

Candidates must:

a. have formal qualification to practise as a microbiologist/technologist with appropriate knowledge of poliovirus and its control in relevant working environments;

b. have worked within a relevant laboratory/ vaccine production facility or clinical trials environment for a minimum of three years; and

[15] Applicants without applicable tertiary education may be considered if they are able to demonstrate completion of work experience and other personal development activities (e.g. participation in substantive and recognized training/ competency programmes) that provide communication, technical and/or business as well as analytical skills necessary to conduct CCS audits.

[16] Applicants who do not meet formal requirements for risk management may be considered if they are able to demonstrate completion of additional training programmes, membership in competency-based associations, work experience and other personal development activities that provide communication, technical, business and analytical skills necessary to conduct and/or manage CCS audits.

c. have worked in a capacity providing audit/ oversight activities associated with the conduct of relevant duties for a minimum of three years.

Engineering principles and concepts

Candidates must:

a. have formal tertiary education[17] with resulting qualifications in engineering or facilities management relevant to containment, including pertinent aspects of laboratory/ production engineering controls;

b. have worked within a laboratory/vaccine production facility for a minimum of two years with engineering systems used to control biorisk (e.g., air handling systems, effluent/ room decontamination, closed production processes, autoclaves, other relevant equipment and systems); and

c. have worked in a capacity providing audit/ oversight activities associated with the conduct of relevant duties for a minimum of three years.

Emergency preparedness

Candidates must:

a. have formal tertiary education[15] with resulting qualifications in emergency preparedness and response relevant to containment, including pertinent aspects of laboratory/production engineering controls;

b. have worked within a laboratory/vaccine production facility for a minimum of two years in emergency planning and response, including developing plans, managing exercises and simulations, liaising with relevant authorities and developing contingency plans; and

c. have worked in a capacity providing audit/ oversight activities associated with the conduct of relevant duties for a minimum of three years.

Security

Candidates must:

a. have formal tertiary education[15] with resulting qualifications in security management relevant to containment, including pertinent aspects of laboratory/vaccine production environments;

b. have worked within a laboratory/vaccine production facility for a minimum of two years in the area of security issues relevant to biosecurity, including developing security plans, liaising with relevant authorities and developing monitoring and response plans; and

c. have worked in a capacity providing audit/ oversight activities associated with the conduct of relevant duties for a minimum of three years.

3.5 AUDITING EXPERIENCE AND GAPIV TRAINING

Auditor

NACs should ensure that auditors have sufficient auditing experience (at least 3 years) in

[17] Applicants without applicable tertiary education may be considered if they are able to demonstrate completion of work experience and other personal development activities (e.g. participation in substantive and recognized training/ competency programmes) that provide communication, technical and/or business as well as analytical skill necessary to conduct CCS audits

bio-risk management or a related field (GMP, GLP, biocontainment, ISO45001:2018, ISO 9001 including institutional practices, etc.) as outlined in section 1.6. Additionally, while only the lead auditor on a CC audit must have undergone GAPIV training, all auditors having undergone the training is ideal.

Lead auditor

To be recognized as a CCS lead auditor, an auditor should also:

a. demonstrate competence in effective leadership and efficient management of bio risk management audits or audits done in a related field, including all aspects of planning, execution, reporting and required leadership and communication skills;

b. have demonstrable ability to draw rational and evidence-based conclusions regarding the facility's biorisk management systems in relation to GAPIV requirements; and

c. have undergone GAPIV training

A lead auditor may be deemed qualified by the NAC after demonstrating the necessary experience, education, and required GAPIV training. Specific competence, to be verified by the NAC, should be demonstrated in relevant activities[18], including conducting opening and closing meetings, categorizing and presenting findings, and communicating with facility management and other relevant stakeholders.

3.6 PERSONAL ATTRIBUTES

In addition to education and auditing experience, auditors must demonstrate appropriate personal attributes, including being:

- **open minded** – willing to consider alternative ideas or points of view;
- **diplomatic** – tactful in dealing with people;
- **tenacious** – persistent, focused on achieving objectives;
- **decisive** – able to reach timely conclusions based on logical reasoning, objective evidence and analysis;
- **self-reliant** – able to act and function independently while interacting effectively with others;
- **ethical** – fair, truthful, sincere, honest and discreet;
- **morally courageous** – willing and able to act in a fair and impartial manner, despite pressure generated by the need to take what may often be unpopular decisions that can lead to confrontation;
- **organized** – able to effectively prioritize, in relation to the use of time and other resources, to ensure the scope of work is competed effectively and areas of risk are addressed appropriately; and
- **communicative** – able to communicate well (talking, writing and listening).

The evaluation of personal attributes should be performed by the NAC in a structured and documented manner[19], with the creation and maintenance of appropriate profiles and records[20]. They may mainly be assessed by interview, feedback from witnessing auditors

[18] Countries that will experience limitations in terms of numbers of PEFs and in the ability to qualify/maintain the qualification of auditors may wish to consider maintaining competence through involvement in other similar activities (e.g. relevant containment-related and/or Good Manufacturing Practice inspections). The involvement of auditors who fall into this category in GAPIV audits is subject to approval by the NAC on a case-by-case basis

[19] This can be assessed by lead auditors as part of the auditor monitoring. Auditors unable to demonstrate these capabilities may either fail to become qualified or lose the status of auditor.

[20] This is described in Annex D of ISO 17021-1:2015 (5).

during audits, and feedback from facility personnel or others associated with the performance of the audit.

3.7 AUDITOR QUALIFICATION AND REQUALIFICATION

CCS auditor application[21]

While in the past it has been customary to request for CVs of proposed auditors, from this point forward, the Audit Team Membership Application form should be used. Particular attention should be given when filling in page 5 (auditing experience).

The NAC should review and approve applications and maintain a register of qualified auditors, trainers used by the NAC to maintain auditor competency, and technical experts.

CCS auditor requalification

The NAC should establish a system to formally review auditor and lead auditor qualifications according to a three-year cycle, and to evaluate whether an auditor's registration should be renewed after the first three years. The review should address the activities of auditors, feedback from colleagues/facilities and other relevant information.

CCS auditor performance monitoring

Failure to meet the required levels of performance and moral/ethical standards required by the CCS may result in additional monitoring activities by the NAC, the production of an action plan with a detailed root-cause analysis and targeted improvements, and/ or removal/suspension of the auditor qualification where deemed necessary. NACs are responsible for ensuring that the performance of personnel providing audit activities is appropriately monitored, and the relevant competencies of audit teams are maintained by monitoring and evaluating.

The NACs' review of the overall conduct of the audit by the auditors must encompass:

A. The review of findings, with indicators of adherence to due process and the quality of audit inputs and outputs, including:

- completeness of audit plans and reports;
- clear and unambiguous description of NCs and other findings with adequate references and objective evidence;
- numbering of findings, correctness of classification, ratio between NCs and other findings;
- correctness and completeness of records;
- feedback to auditors;

B. direct and indirect feedback from team leaders, facility representatives, NACs, WHO or other observers, including, where relevant, documented records of feedback and other communications maintained to support the review and approval process, and analysed information with positive as well as potentially negative feedback, such as:

- information from satisfaction forms/surveys;
- feedback from witness audits;
- complaints from facilities/other relevant parties;
- follow-up interviews based on the above or generated by other means;
- feedback to auditors;

[21] Countries may have divergent schemes relating to the identification of candidates and their qualification as auditors, which may include the designation of inspectors and other similar mechanisms. These mechanisms may be deemed appropriate provided they meet the intent of the CCS.

C. the review of records generated as part of the audit process, forming part of the annual and three-yearly reapproval by the NAC of the qualifications of CCS auditors, including:
   - audit reports with findings and associated information.
   - tracking forms, attendance lists, records of documents reviewed, etc.
   - continuing professional development records with certificates attained and other pertinent information.
   - feedback to auditors; and
   - information applied to the reapproval process.

3.8 TRAINER QUALIFICATIONS TO PROVIDE GAPIV TRAINING FOR AUDITORS

If the NAC decides to conduct its own GAPIV training for auditors, the trainers appointed to provide GAPIV training courses must be qualified as lead auditors by their respective NAC. The training should use, at a minimum, the structure and curriculum of the WHO-endorsed GAPIV Training for Auditors. Mentorship programmes or other means of providing auditors-in-training with opportunities to benefit from the experience of more senior auditors as organized by the NAC are also encouraged to ensure the development of competent auditors. To ensure global harmonization of auditor training, the NAC should submit or present their training curriculum to the GCC–CWG for feedback.

3.9 CALIBRATION OF CCS DELIVERY

All auditors should participate in at least one day of calibration activity per year. Calibration activity meetings ensure that auditors are aligned and make similar judgements on what is acceptable and unacceptable practice, that they review their findings and categorizations, and update any interpretations made by technical review teams, as well as other similar activities. This activity can be face-to-face or through telephone or videoconferencing. WHO may organize the calibration meetings with NAC representatives, auditors and technical experts.

3.10 TECHNICAL EXPERTS

Although technical experts do not need to qualify as auditors, they should at a minimum meet the education and work experience requirements in their specific discipline, described in section 3.4. They should not act as auditors or lead auditors or work independently during audits. They should remain under the supervision of qualified auditors at all times and must meet the necessary requirements relating to confidentiality and potential conflicts of interest. The auditors must ensure that the knowledge provided by the technical experts applies in the specific context of GAPIV audits in keeping with the CCS.

3.11 AUDIT TEAM APPROVAL

The NACs approve the auditors for their country and determine the audit team appropriate for each audit. The GCC–CWG has the role of reviewing the full audit team prior to the start of any audit activities, through review of the Containment Audit Proposal submitted by the NAC. GCC–CWG review of the audit team has the goals of ensuring auditors are competent and timelines aligned with global deadlines and of reducing delays in certificate issuance due to the need for additional information on the audit team members following application submission. During this step, the GCC–CWG will either endorse the audit team or provide recommendations for changes before the initial ICC, initial CC, periodic, or other audit. While Audit Team Membership Application forms are accepted as part of a Containment Audit Proposal, the NAC is also free to submit audit team member applications to the GCC–CWG on an ad hoc basis for endorsement. This is encouraged in order to avoid delays in audit activities.

4.

Conducting CCS Audits

This section provides detailed instructions on conducting a CCS audit in support of the containment certification process. Audit planning activities should begin once the contract/agreement between the NAC and the CP-holding facility has been signed.

4.1 AUDIT TEAM SELECTION AND PREPARATION

The audit team's proper composition is key to ensuring appropriate audits can be conducted and to providing assurance that consistent criteria are applied in an equitable manner across different facilities and regions. The audit team's roles and qualifications are defined in section 3.

A minimum of two individuals, acting in the capacity of either team leader, lead auditor or auditor are required to perform CCS audits. The audit team may be comprised of at least one lead auditor as team leader and at least one additional lead auditor/auditor. Technical experts can be included to address specific areas of specialization, provide local knowledge and assist in the interpretation of local practices and conditions. However, these experts are not qualified auditors and must operate at all times during the audit under the supervision and guidance of a lead qualified auditor. The team should also include locally qualified auditors and/or technical experts who are aware of local laws, regulations and practices. The team should include members familiar with the type of facility being audited (e.g., vaccine manufacturing, research, storage facility, etc.). Audit teams should be nominated by the NAC, involving suitably qualified personnel listed as GCC–CWG-endorsed auditors and technical experts.

4.2 AUDIT PLANNING

Before the start of an audit, the team leader should obtain all relevant information, including:

- at the subnational level:
    - documentation of immunization coverage and environmental safeguards, as described in GAPIV (in coordination with the NAC);
- at the facility level:

- copy of the containment certification contract/agreement between the NAC and the facility;
- the containment certification application form (see the Certificate of Participation (CP) Application Form (Initial- and Re-application); Interim Certificate of Containment (ICC) Application Form (Initial and Extension); and Certificate of Containment (CC) Application Form (Initial and Recertification);
- requested documents (see the Document Request Form (initial, periodic or recertification audit for ICC or CC));
- any reported changes to the scope of certification, if applicable;
- previous audit reports and lists of findings, if applicable; and
- previous Corrective and Preventive Action Plan submittals, if applicable.

The team leader should also correspond with the facility to:

- confirm the availability of key facility staff and the purpose and date of the audit;
- provide the list of audit team members;
- facilitate audit team entry into the facility for all days of the audit (with respect to security issues etc.);
- inquire about any vaccination requirements for entry into the rooms being audited; provide the Audit Plan; and
- discuss a possible audio- or video recording of the closing meeting.

Because of the challenges that arise from visiting facilities prior to the initial full certification audit, especially when international teams of auditors are involved, preparations may include the off-site review of documents, as opposed to conducting that task during an initial visit or gap assessment. The objectives of this activity are to assess the documented compliance of the facility's biorisk management system, identify areas to focus on during the audit, and allow for the development of the Audit Plan. Unless otherwise agreed, the facility is advised to submit all requested documents (see the Document Request Form (initial, periodic or recertification audit for ICC or CC)) to the team leader at least 20 days before the audit, or as determined by the NAC.

The team leader is responsible for preparing the Audit Plan (see the Audit Plan (initial, periodic, upgrade to CC from ICC or recertification audit for ICC or CC)) and for assigning responsibility for specific areas or elements of GAPIV to particular individuals, although all team members are expected to contribute to all elements where appropriate. The plan is sent to all audit team members, and their respective roles and responsibilities are discussed and clarified where necessary before it is advised to be shared with the facility at least 20 working days before the audit, or as determined by the NAC.

4.3 INFORMATION REQUIREMENTS

A typical list of documents for review[22] (see the Document Request Form (initial, periodic or recertification audit for ICC or CC)) at the beginning of the audit is shown below, with ideally one copy distributed to each auditor unless delivered electronically. The NAC determines how documents are to be delivered by the facility (e.g. digitally). Please note that an auditor may ask for additional documents before auditing, and that the documents requested for review before or during an audit are determined by the audit team in consultation with the NAC. The documents to be reviewed may include the following:

[22] Before any documents are shared, all security requirements for the transport, transfer and handling of sensitive information must be met.

- an organizational chart outlining the biorisk management-related roles and responsibilities;
- a register of applicable laws, standards and guidelines;
- biosafety/biosecurity manuals and associated plans;
- accident/incident reports relevant to poliovirus containment;
- the list of contracted services, companies and individuals;
- relevant risk assessments (e.g. those relating to emergency preparedness, procedural controls, the design and operation of the plant and equipment, decontamination measures, security measures);
- a map/floor plan, including any relevant support areas (e.g. plant rooms, storage areas, waste handling/storage locations);
- the minutes of the biosafety committee for the last 12 months;
- biorisk management policies and procedures reflecting the 14 elements within GAPIV;
- internal audit plans and findings from the previous year;
- training plans and competency assessments reflecting biorisk management-related activities;
- emergency plans and records of exercises;
- inventories of poliovirus and related materials (e.g. cultures, waste);
- equipment lists/asset registers;
- facility/equipment certification records;
- data demonstrating building performance (e.g. air flow measurements, performance of autoclaves/effluent treatment plants); and
- building design/commissioning plans.

4.4 AUDIT ANNOUNCEMENT

All audits should be planned and announced, with the exception of those for which the relevant NAC considers there is a compelling reason to conduct an unannounced audit.

4.5 ON-SITE AUDIT ACTIVITIES

Conducting the opening meeting

An opening meeting should be held, and attendance recorded (see the Audit Attendance Sheet). The opening meeting provides an opportunity for the facility and audit team to exchange information and become familiar with the nature of the facility and associated work, as well as finalize the Audit Plan and ensure the facility is fully briefed on the auditing process. The opening meeting ideally should not extend beyond one hour unless extenuating circumstances dictate otherwise. A typical list of activities for the opening meeting includes:

- introductions of the representatives from the facility and the audit team members, stating associated roles and responsibilities;
- confirmation of the scope and purpose of the containment certification;
- a final review and agreement of the Audit Plan (although adjustments should be minor since it will have been agreed in advance).

- confirmation of the communication channels and timings (e.g. any concluding summaries and information on the closing meeting);
- a brief explanation of the audit process, including reporting activities and opportunities for feedback between the parties;
- clear information on all the areas and locations, activities and departments that will be audited and the people involved;
- a review of the confidentiality arrangements and how they should be handled, including the management of documents during the audit and restrictions on the use of cameras and other recording devices;
- the location of meeting rooms for the team to conduct interviews and to meet privately when required (e.g. during lunch breaks and to prepare for the closing meeting);
- communication needs in terms of telephone/ Internet connections, use of projectors, etc.;
- information on how findings will be categorized and reported, together with the sequence of events leading to the decisions around the issuance of certificates;
- the language to be used and translation arrangements where applicable;
- a determination of how the facility will ensure that the auditors can obtain the copies of material, records and other information as needed;
- the names and contact numbers of the key participants, guides and other relevant personnel; and
- information on safety and security while on-site, including emergency plans and response measures.

Conduct during the audit

During the audit, interviews will be conducted to assess the mechanisms the facility has set in place to ensure compliance with GAPIV requirements. Representatives who are best placed to discuss certain elements will be invited for interviews that will be scheduled as part of the planning process. The facility is responsible for ensuring the relevant parties attend these interviews to guarantee the audit process is conducted effectively with appropriate access to the required personnel and information.

Once an overview of the management system has been gained through the interviews and document reviews, relevant areas of the facility will be visited in line with the plan. These zones may include administrative areas, laboratories, animal facilities, production areas and associated support spaces, depending on the nature of the facility and the work carried out. Areas to be visited should be prioritized based on risk; those listed in the plan may be amended considering information derived from the interviews and on-site document reviews. The facility is responsible for ensuring reasonable access to all requested areas, and for the safety and security of the audit team and other personnel. This responsibility includes providing information on vaccination requirements and other measures of relevance. *(Note: vaccination needs and other immunizations, depending on the facility, should already have been determined and met as part of the planning process.)*

Other than during private discussions, the audit team should be accompanied by assigned facility staff as the audit is conducted. The audit team should meet with facility leadership at least daily (normally in the late afternoon) to provide an update on the status, areas of potential concern and additional lines of investigation that may be required. During this time, the facility may also present additional information or offer explanations concerning the potential issues identified. Ad hoc team meetings may also be held as needed, should significant issues arise during the course of the audit.

Although non-consultative information may be provided upon request (e.g. sources of potentially useful information), neither auditors, technical experts, translators nor observers should assume the role of consultant. Where suitable, however, appropriate individuals (e.g. auditors, technical experts) may educate the facility staff on aspects of GAPIV and CCS requirements and their application to the audit processes. In case of doubt, all parties should consult with the team leader before offering advice and clarification. No auditor, technical expert or observer should attend an audit if they have worked in a staff or consultancy capacity or similar role, where conflicts of interest may be of concern, within a period of three years prior to the date of the containment certification contract/agreement with the facility. Additionally, no PEF member may serve as a member of any NAC.

Audited documents

The team leader should appoint a member of the team to maintain a register of documents provided by the facility (see the Document Review Register (initial, periodic or recertification audit for ICC or CC)) and ensure all documents are treated with due care, are accounted for and are returned at the end of the audit, unless written permission has been given to the audit team to retain them. Permission must also be sought before copying or removing any documents from the site during the audit.

Interviews

Interviews are used to gain an understanding of the systems adopted by the facility and associated organization to ensure compliance against GAPIV requirements and to identify lines of enquiry and focus areas for further investigation. Auditors should be skilled in appropriate interview techniques and maintain legible and comprehensive notes of interviews, particularly those relating to areas that may subsequently be used as a basis for findings. Notes should include the date, time and location, full name and title of the person(s) interviewed and key points made and/or topics discussed. To the fullest extent possible, quotes should be noted from interviewees addressing key points of relevance. In addition to formal element-related interviews, informal interviews may be conducted with facility personnel during site tours; these personnel should be made aware that they are being questioned as part of a formal audit process. Notes should also be maintained for these interactions.

Data from interviews should be integrated with information emanating from observations and document reviews in arriving at and reporting findings. Information from observations during facility tours and from document reviews should also be subject to appropriate note taking by auditors.

Facility tours

Once an overview of the proposed control measures has been achieved through interviews, visits to the facility should be conducted to observe the physical conditions, access local records where appropriate (e.g. paper or computer-based records), interview personnel at the work site, and check whether the controls described in the management system documentation are reflected in the actual facility and associated practices. This is a critical aspect of the audit since the main objective is to ensure that containment measures are being effectively implemented and maintained. Although the areas to be visited will be outlined in the Audit Plan, amendments may be required based upon prior interviews or other relevant sources of information.

Potential focus areas for tours include, but are not limited to:

- poliovirus storage, including repositories, bulk storage, culture collections, inventories and associated information systems;
- animal handling areas and associated equipment (e.g. isolators);

- emergency response personnel, systems and associated supplies;
- areas where medical surveillance/treatments may be conducted;
- staff meeting rooms, dining rooms and rest areas;
- laboratory and production spaces under containment;
- ancillary laboratory and production areas not under containment;
- quality control facilities;
- goods inwards/outwards and areas where transportation may be arranged;
- specimen packing and unpacking areas;
- maintenance workshops with associated records and personnel;
- the heating, ventilation and air conditioning system, including related control systems;
- the effluent decontamination plant, including related control systems;
- laundry and clothing storage and decontamination areas;
- personal protective equipment stores;
- room decontamination systems;
- equipment airlocks and decontamination systems, including change areas and showers;
- waste handling and disposal systems; on- site incinerators;
- dosing and treatment systems used in decontamination;
- training facilities; and
- security control rooms and associated personnel.

4.6 GENERATING FINDINGS

The team leader should coordinate regular discussions among the audit team during the course of the audit to review information being gathered and to provide direction in terms of lines of investigation, additional evidence that may be required and other relevant factors. Each auditor is responsible for identifying findings in relation to the facility's ability to fulfill requirements under GAPIV. Nonconformities (NCs) are deficient practices that should be cited when objective evidence exists that a requirement has not been addressed (intent), a practice or condition differs from the defined system (implementation), or the system is not effective (effectiveness). NCs should be agreed where possible with the auditee during the course of the audit, and any areas of debate or disagreement addressed as far as reasonably possible during the audit.

An NC should clearly identify:

1. the requirement that has not been met, including citing the applicable GAPIV subelement, based upon:
    - One or more elements of the containment certification/verification criteria;
    - Facility procedures that are not followed (process, product, service specification);
    - An applicable regulation that is not being met
2. deficiencies supporting the NC categorization, including:
    - Identification of the location, process, activity; and
3. objective evidence, including:

- Reference to specific documents, observations and/or verbal evidence in support of the identified failing

The team leader will base the findings on input from the team but makes the ultimate decision regarding the issuance and categorization of findings. Information required for the verification of findings should be collected and analysed prior to the closing meeting; it is the responsibility of each auditor to ensure the collection of appropriate evidence supported by documentation, together with interview notes and records of observations.

In the event the organization claims that an NC that was identified before the audit has been closed, the team leader may consider whether the corrective action is appropriate, has been applied systematically and implemented effectively. If the conclusion is that this is the case, a decision may be taken not to allocate an NC, provided there is sufficient evidence and confidence that the issue will not recur.

Findings should be presented as falling into one of the following categories:

Noteworthy efforts

Noteworthy efforts are described as:

- the adoption of best practice
- demonstrated improvement
- high levels of commitment
- motivation
- system optimization.

Noteworthy efforts should be reported at the closing meeting and in the audit report (see the Audit Report (initial, periodic, upgrade to CC from ICC or recertification audit for ICC or CC)).

Nonconformities: Category 1 (major)

An NC should be categorized as major (NC1) when there is:

- an absence of one or more required system elements, or a situation that raises significant doubt that the activities will meet the specified requirements;
- a group of Category 2 NCs indicating inadequate implementation or effectiveness of the system relevant to one of the standard's requirements;
- a Category 2 NC that is persistent (or not corrected as agreed by the facility), thus upgraded to Category 1; and/or
- a situation that on the basis of available objective evidence may directly lead to an unacceptable risk of breach of containment measures described in GAPIV.

Nonconformities: Category 2 (minor)

An NC should be categorized as minor (NC2) when a facility's demonstrated lapse of discipline or control during the implementation of system/procedural requirements does not indicate a system breakdown or raise significant doubt that controls will meet the specified requirements. In this case the judgement can be that, despite the issues identified, the overall system requirement is defined, implemented and effective.

Nonconformities under an ICC (ICC-NC)

Any NC1 which cannot be closed out within 90 calendar days due to the need for major structural work or other similar barriers that prevent timely closure is considered an ICC-NC. An ICC application may still be endorsed by the GCC provided:

- a detailed, documented, independently peer-reviewed risk assessment associated with the ICC-NC is made available, reviewed by the lead auditor and approved by the NAC as part of the process to recommend the issuance of the ICC;

- adequate alternative measures of compliance are identified and put in place following an independently peer-reviewed risk assessment and are approved by the lead auditor and the NAC as part of the process to issue an ICC and recommend to the GCC–CWG that it be endorsed.

The independent peer review of the risk assessment associated with the ICC-NC is the responsibility of the PEF. Following the development of a documented risk assessment, the PEF should identify a peer reviewer, independent from both the PEF and the NAC, with expertise in the subject area in which the ICC-NC was found. This peer reviewer is responsible for evaluating the efficacy of the chosen adequate alternative measures in minimizing the biorisk associated with the ICC-NC. The peer reviewer's conclusions should be communicated as part of the risk assessment back to the PEF. If the peer reviewer finds the adequate alternative measure to be insufficient, the facility must make adjustments until the peer reviewer and facility are in agreement on appropriate adequate alternative measures of compliance. The outcome from the risk assessment and peer review, including any follow-up discussions and decisions, must be communicated to the lead auditor for agreement. Once the lead auditor has approved all adequate alternative measures and the Corrective and Preventive Action Plan, these decisions and all associated documentation must be submitted to the NAC for approval. The NAC then submits all documentation and conclusions to the GCC–CWG as part of the ICC application package for endorsement.

Nonconformity closure for a CC

The issuance of a CC requires that a PEF is fully compliant with the requirements in GAPIV according to the CCS. While NCs may be identified during an audit for a CC, they should be closed out before a CC application is submitted. No adequate alternative measures are acceptable under a CC.

After obtaining a CC, a facility must maintain conformity. Recognizing that NCs may be identified during periodic audits, these NCs must be closed as described below (section 4.7) following timelines determined by the NAC and audit team leader in order to maintain CC conformity.

Observations

An observation is not an NC but can lead to one if allowed to continue uncorrected. It is also an existing condition without adequate supporting evidence to indicate that it constitutes an NC.

Opportunities for improvement

An opportunity for improvement denotes areas and/or processes that may meet the minimum requirements of GAPIV but that could be improved. It may be system- or performance-related and is normally specified based on the experience of the audit team, the knowledge of international best practice in other facilities or the practices within the facility's other units/departments. This category may be used by auditors and NACs to communicate with facilities but will not be considered by the GCC–CWG as part of the audit report.

Closing meeting

The team leader is responsible for organizing the presentation at the closing meeting, including determining who will present the individual findings, and ensuring all the findings appear in the report. The closing meeting can be attended by those the facility deems appropriate. It provides evidence in fact-based presentations of any noteworthy efforts, NCs

and observations. All NCs must be accompanied by an explanation as to why they constitute a nonconformance with the given requirement.

The closing meeting may be recorded at the discretion of the team leader. In these cases, the team leader must obtain a copy of the recording in its entirety before leaving the facility and must also provide a copy to the NAC.

4.7 REPORTING AND FOLLOW-UP

Post-audit activities

The team leader is responsible for coordinating the audit report and producing a draft and final report (see the Audit Report (initial, periodic, upgrade to CC from ICC or recertification audit for ICC or CC)). The objective is to report the findings of the assessment in a manner that translates into measurable and timed actions for the PEF, including closure of any NCs.

The Audit Report contains the following information:

- a table of the areas of the facility audited and activities performed in those areas, with enough detail to give the GCC–CWG context for the audit findings;
- a summary table showing the number, types and categories of findings; and
- a subsection for each GAPIV element with key audit findings, noteworthy efforts, observations and opportunities for improvement in that element and follow-up activities planned.

The Corrective and Preventive Action Plan contains the following information:

- audit date
- audit type (e.g. gap assessment, initial, periodic)
- list of NCs
- level and type of NCs
- status of NCs (e.g. open, closed)
- clause against which the NCs were generated
- immediate actions required
- root-cause analysis relating to the NCs
- proposed actions to close the NCs
- dates on which the actions should be initiated and completed
- date on which corrective action is accepted in principle
- verification activity

Time to prepare the report should be incorporated into the audit plan. The team leader should provide a draft for circulation between the audit team members to ensure a draft report is completed within a maximum of 20 working days post-audit, or as determined by the NAC. The completed report should be sent to the facility via the NAC. Any queries should be addressed to the appropriate team leader, who should coordinate the response prior to submission of the document for internal review by the NAC. Immediate follow-up with the facility will be conducted as follows:

The audit findings and Corrective and Preventive Action Plan (see the Audit Findings and Corrective and Preventive Action Plan) should be submitted to the facility with the sections on the number and type of NCs completed by the team leader. The team leader should include the following information in the Corrective and Preventive Action Plan form:

- audit date
- audit type (e.g. gap assessment, initial, periodic)
- list of NCs and observations
- level and type of NCs
- status of NCs (e.g. open, closed)
- clause against which the NCs were generated
- immediate actions required

The facility should then update the Corrective and Preventive Action Plan by completing the relevant sections relating to the root causes, corrective actions and proposed dates by when the actions will be completed. This response from the facility is advised to be submitted to the team leader within 30 working days of receipt of the Audit Findings and Corrective and Preventive Action Plan, or as determined by the NAC. The PEF should complete the following information on the Corrective and Preventive Action Plan form:

- root-cause analysis relating to the NCs
- proposed actions to close the NCs
- dates on which the actions should be initiated and completed
- date on which corrective action is accepted in principle

Once the facility has completed the Audit Findings and Corrective and Preventive Action Plan, it will be reviewed by the team leader for completeness and to ensure that the actions are appropriate, sufficient and timely. If additional actions are considered necessary, they are expected to be communicated to the facility within 10 working days and responses received within a further 10 working days, or as determined by the NAC. In consultation with the NAC, the team leader will then provide the following details to the form:

- verification activity
- dates on which each individual finding will be closed

When agreement has been reached regarding the required corrective actions, the following process should be followed depending on the NC categorization:

Category 1 (major)

- The corrective actions for NC1s normally require on-site verification, although under exceptional circumstances the team leader may determine that the submission of documentary evidence is sufficient.
- Corrective actions must be completed within 90 calendar days, and submitted documentation must include:
    - evidence of the actions taken
    - the reasons they are considered to effectively address the root causes of the issues identified; and
    - how they have been adequately implemented to prevent recurrence.

Verification of corrective actions will be determined jointly by the lead auditor and the NAC. The lead auditor then submits a report outlining the corrective actions taken and verified for each nonconformity to the NAC for transmission to the GCC–CWG. This report must be verified by the GCC–CWG before an ICC or CC is endorsed.

Although mechanisms are established for the verification of closing-out of nonconformities such as the periodic audits in the second and third year of the ICC, additional frequency of such reporting and auditing may be established by the NAC in conjunction with the GCC–CWG depending on the nature of the nonconformity. No ICC or CC should be issued until

the NC1s have been verified as being effectively closed. Should a follow-up visit be required to witness the closure of the NCs, an audit plan should be submitted for the visits as per an initial audit, but with a scope and audit team suitable to the nature of the NCs. Appropriate records should be kept of the planning, execution and reporting of any follow-up visit.

Category 2 (minor)

The corrective actions for NC2s do not normally require on-site verification, although under exceptional circumstances the team leader may determine that the submission of documentary evidence is insufficient (e.g. in the event of large numbers of NC2s). The Corrective and Preventive Action Plan must be submitted within 90 calendar days and must include:

- the actions that will be taken;
- the reasons they are considered to be suitable to effectively address the root causes of the issues identified; and
- how they will be adequately implemented to prevent recurrence.

The verification of corrective actions to address nonconformities will be done by the lead auditor at the first periodic audit or as determined by the lead auditor following the identification of the NC2.

The lead auditor submits a report outlining the corrective actions taken and verified for each nonconformity to the NAC. The report must include:

- evidence of the actions taken;
- the reasons they are considered to effectively address the root causes of the issues identified; and
- how they have been adequately implemented to prevent recurrence

This report must be verified and endorsed by the NAC and submitted to the GCC–CWG before an ICC or CC application may be endorsed.

Although mechanisms are established for the verification of closing-out of nonconformities such as the periodic audits in the second and third year of the ICC or CC validity, additional frequency of such reporting and auditing may be established by the NAC in conjunction with the GCC–CWG depending on the nature of the nonconformity. No ICC should be issued until an agreed Corrective and Preventive Action Plan is in place for the closure of the NC2s, approved by the NAC. No CC may be issued while NC2s remain open. Should a follow-up visit be required to witness the closure of the NCs, an audit plan should be submitted for the visits as per an initial audit, but with a scope and audit team suitable to the nature of the NCs. Appropriate records should be kept of the planning, execution and reporting of any follow-up visit.

Nonconformities under an ICC (ICC-NC)

The corrective actions for ICC-NCs require on-site verification. Corrective and Preventive Action Plans must be submitted as part of the CC application, and must include:

- evidence of the actions taken
- the reasons they are considered to effectively address the root causes of the issues identified; and
- how they have been adequately implemented to prevent recurrence.

Verification of corrective actions will be performed by the lead auditor, approved by the NAC and transmitted to the GCC–CWG before a CC may be endorsed. The Corrective and Preventive Action Plan and evidence of closure of NCs are then transmitted to the GCC–

CWG for endorsement.
Adequate alternative measures must be in place while work to implement corrective actions is ongoing. The PEF must submit a report to the lead auditor which includes:

- Evidence of an independent peer reviewed risk assessment of identified ICC-NCs
- The proposed adequate alternative measures; and
- The reasons they are considered to effectively minimize the biorisk associated with the ICC-NCs, according to the risk assessment.

The lead auditor and the NAC approve adequate alternative measures deemed satisfactory, and submit relevant evidence of the process taken to determine and implement these measures to the GCC–CWG as part of the ICC application.

Ineffective corrective action

In the event that corrective actions are late or considered inadequate, the following measures may be instituted:

NC1 including ICC-NC – During an initial or recertification audit, the NAC should evaluate the circumstances and determine the acceptability of the proposed course of action. Alternatively, depending on the nature and severity of the deficiencies identified and the associated response, a decision may be taken to remove the facility as an applicant for containment certification and close the containment certification process. Should the issues arise during a periodic audit, the NAC may additionally choose to suspend or revoke the certificate. Under both eventualities, a re-audit may also be required. As ICC-NCs are a class of NC1s, all of the above applies in the same way to instances of ineffective corrective action for an ICC-NC.

NC2 – Should issues arise during the audit, an NC2 may be escalated to NC1 and/or the NAC may additionally choose to suspend or revoke the certificate. Under both eventualities, a re- audit may also be required. If an extension has been granted and the facility fails to comply with the new due date, appropriate action should be carried out without delay.

4.8 CONTAINMENT CERTIFICATION REVIEW AND APPROVAL

Once the facility has received the audit findings and actions are addressed to the satisfaction of the team leader/NAC, the NAC should perform a review of the overall conduct of the audit and of the findings in view of recommending the issuance of a certificate. The NAC's review should be carried out by a representative of the NAC who is independent of the audit team, to ensure due process has been followed and all relevant information will be provided to the GCC–CWG for review. The technical review is particularly important in the event that an audit team is not an integral part of the NAC itself (e.g. audits performed on a contract basis). This review should be shared with the GCC–CWG, along with the following documentation:

- the Audit Plan;
- the Audit Report and any special follow-up reports that may have been required;
- the Audit Findings and Corrective and Preventive Action Plan; and
- the recommendation from the NAC regarding the award of the ICC/CC.

The GCC–CWG will review the reports and other submitted documentation to ensure the following criteria were met:

- the facility was able to demonstrate that the biorisk management system

conformed to all applicable GAPIV requirements;

- an independent and competent audit team conducted the audit;
- the audit was conducted in accordance with the requirements of this document; and
- objective evidence was identified and presented to demonstrate that all NCs were closed.

After the review, the GCC–CWG will generate a report to the NAC endorsing or not endorsing the issuance of the ICC/CC.

Achieving a Certificate of Containment

A CC application can only be submitted to the GCC–CWG for endorsement when a facility has no open NCs. While NCs may be identified during the audit, these must be closed before an application can be endorsed. No ICC-NCs are permissible under a CC. The GCC–CWG will endorse the issuance of a CC for facilities which have closed all outstanding NCs per GAPIV requirements with an audit conducted according to the standards described in this document.

5.

Costs and charges

The NAC must determine the costs of the containment certification activity and how the costs will be met. Unless otherwise specified, activities associated with the costs and charges relating to the CCS should be met by the facility or other nominated parties.

See Annex 1 for guidance on determining costs associated with audits, formerly the Man-Day Cost Guidance.

6.

Forms and templates

The following GAPIV Containment Certification forms are available on the polio containment page of the GPEI website to support the roll-out and implementation of the certification process:

1. Certificate of Participation (CP) Application Form (Initial- and Re-application)
2. Containment Audit Proposal
3. Audit Report (initial, periodic, upgrade to CC from ICC or recertification audit for ICC or CC)
4. Audit Plan (initial, periodic, upgrade to CC from ICC or recertification audit for ICC or CC)
5. Interim Certificate of Containment (ICC) Application Form (Initial and Extension)
6. Audit Findings and Corrective and Preventive Action Plan
7. Certificate of Containment (CC) Application Form (Initial and Recertification)
8. Audit Team Membership Application Form
9. Auditor Log
10. Auditor Monitoring Report
11. Document Request Form (initial, periodic or recertification audit for ICC or CC)
12. Document Review Register (initial, periodic or recertification audit for ICC or CC)
13. Audit Attendance Sheet

References

1. World Health Organization. WHO Global Action Plan for Poliovirus Containment, fourth edition (GAPIV). Geneva: World Health Organization; 2022.

2. World Health Organization. 14th Meeting of the Global Commission for the Certification of Poliomyelitis Eradication (GCC), September 2015 – Report.

3. World Health Organization. 15th Meeting of the Global Commission for the Certification of Poliomyelitis Eradication (GCC), December 2016 – Report.

3. Occupational Health and Safety Assessment Series (OHSAS). Occupational health and safety management systems – Requirements with guidance for use. 45001:2018. Geneva. ISO; 2018.

5. International Organization for Standardization/International Electrotechnical Commission (ISO/IEC). Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements. 17021-1:2015. Geneva: ISO/IEC; 2015

Annex 1: Costs and charges guidance

The lead auditor or audit team and NAC should determine the appropriate duration that would be required to implement the different CCS activities requiring but not necessarily limited to on-site presence. This determination should take into consideration a number of factors involving the facility such as size, scale, complexity, and physical location/layout and the national auditing capacity such as the presence or absence (in the case the auditing competency is determine as the audit team as a whole) of a lead auditor, number of audit team members including technical experts, etc.

The outcome from this determination should be used in justifying the duration of the audit and other activities, audit team members, etc. during the submission of a containment audit proposal for an ICC or CC and as part of the ICC or CC application package to support the audit plan.

This document provides guidance in the planning of the different audit activities to NACs including the allocation of resources for the conduct of these activities. The conduct of these activities will incur costs and charges and unless otherwise specified, such costs and charges relating to the CCS should be met by the facility or other nominated parties.

Although there will be additional resources needs for the maintenance of the NAC in relation to the CCS (e.g., sustaining national level capacity in performing CCS audits and other associated activities in the CCS cycle, etc.) this chapter specifically addresses the planning, execution and follow-up of pre-, audit- and post-audit activities associated with the CCS.

Initiation and planning

This will largely be conducted by the lead auditor. However, other team members may also be required to provide input to the schedule, discuss focus areas, review documents, etc. No specific time allocation is proposed for this activity as this will be at least partly dependent on the nature of the facility, the need for up-front document review, together with the familiarity of the audit team with the facility and other factors until the point an agreement is reached between the facility, lead auditor or audit team and the NAC on the audit plan. However, this area should be formally addressed, and information presented as part of certification reports to the GCC in order to demonstrate that adequate planning did take place, including allocation of adequate resource.

Performance

This is a highly subjective area and required effort will be based on a number of factors, including the size, scale, complexity, and physical location/layout of the facility/facilities, the previous conduct of initial visits or gap assessment, etc. As an approximate guide and depending on the facility-type (laboratory, vaccine production, storage-only), approximately one-half day should be allocated for each biorisk management element described in GAPIV for the first full scope audit. How this effort is allocated may vary based on circumstances and will depend on the major focus areas and relative complexity and volume of the respective elements, but this should allow sufficient time for document review, interviews with personnel, facility tours and associated verification activities.

Reporting and follow-up

This activity will be under the responsibility of the lead auditor and will vary with the number, type of findings and its required frequency for follow-up e.g., one-day on site duration for the monitoring of improvement plans associated with the ICC – NC findings, etc. This would normally require a minimum of one additional man-day but could necessitate more time depending upon the nature and volume of findings and associated action plans, together with the need to discuss and verify NCs, some of which may require

an additional site visit which would be in addition to the time allocations associated with the initial certification visit.

Considerations

There may clearly be a variety of factors that could either increase or reduce the man-days required for a CCS audit, including:

Increased

- The system covers highly complex processes or a relatively high number of unique activities.
- Complicated logistics involve very large sites and/or more than one site or building where work is carried out.
- Need for translation of spoken and written information.
- High degree of national regulation.
- Other additional relevant factors (e.g. need to cover multiple shifts).
- Small number of audit team members

Decreased (Note: maximum reduction 30%)

- Not all elements covered in scope such as in storage-only facilities.
- Maturity of management system and familiarity/experience from previous assessments.
- Auditee preparedness for certification (e.g. initial visits and gap assessments previously performed).
- Low complexity activities including those involving a single generic activity (e.g. storage-only repository).
- Other additional relevant factors.

Any specific considerations leading to either significantly increased or decreased duration should be indicated in the audit report submitted to the GCC. Failure to present a justifiable rationale for audit length may jeopardize GCC's endorsement of a containment certificate.