



Containment Certification
Scheme
to support the
WHO Global Action Plan for
Poliovirus Containment

GAPIII-CCS

Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment

GAPIII-CCS

Containment Certification Scheme (CCS) to support the certification of facilities against the *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII, Annex 2 and Annex 3)*



World Health
Organization

Containment certification scheme to support the WHO global action plan for poliovirus containment.

ISBN 978-92-4-151147-6

© **World Health Organization 2017**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Containment certification scheme to support the WHO global action plan for poliovirus containment. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design and layout: [Paprika \(Annecy, France\)](#)

CONTENTS

Acknowledgements	VI
Abbreviations and acronyms	VII
Definitions	VIII
1. INTRODUCTION	1
1.1 Purpose.....	1
1.2 Maintenance	2
1.3 Background.....	2
1.4 CCS objectives	2
1.5 Nature and type of facilities addressed by the CCS	3
1.6 Roles and responsibilities	3
1.7 Delegation of activities	4
2. CONTAINMENT CERTIFICATION PROCESS	5
2.1 Certificate of participation	5
2.2 Interim certificate of containment.....	6
2.3 Certificate of containment	8
2.4 GCC-endorsed certificates	9
2.5 Modification, suspension, withdrawal, complaints and appeals	9
3. THE AUDIT TEAM	10
3.1 Qualification of auditors and technical experts for GAPIII certification	10
3.2 Audit team roles and functions	10
3.3 Auditor competencies.....	11
3.4 Education and work experience	11
3.5 Auditing experience and CCS training.....	13
3.6 Personal attributes.....	14
3.7 Auditor qualification and requalification	14
3.8 Trainer qualifications to provide GAPIII Training for Auditors	15
3.9 Calibration of CCS delivery.....	15
3.10 Technical experts	15
4. CONDUCTING CCS AUDITS	16
4.1 Audit team selection and preparation.....	16
4.2 Audit planning.....	16
4.3 Information requirements	17
4.4 Audit announcement	17
4.5 On-site audit activities.....	17
4.6 Generating findings	19
4.7 Reporting and follow-up.....	21
4.8 Containment certification review and approval	22
5. COSTS AND CHARGES.....	23
6. CCS FEEDBACK AND REVIEW	24
7. SAMPLE TEMPLATES.....	25
REFERENCES.....	26

ACKNOWLEDGEMENTS

The development of this first edition of the *GAPIII Containment Certification Scheme (CCS)* to support the *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII) (1)* has been made possible through the contributions of the following, whose expertise is gratefully acknowledged:

Paul J. Huntly, Riskren PTE Ltd, Singapore

Jane Toh, Riskren PTE Ltd, Singapore

Nicoletta Previsani, WHO

The contributions of the following reviewers are also recognized with appreciation:

Walter Dowdle, Jackie Fournier-Caruana, Robert Freeman, Mary Louise Graham, Paul Griffiths, Gary Lum, Phil Minor, Steve Oberste, Mark Pallansch, Richard Pebody, Hiroyuki Shimizu, Graham Tallis, Bruce Thorley and Jan-Willem van den Brink.

The *GAPIII Containment Certification Scheme (CCS)* was endorsed by the WHO Strategic Advisory Group of Experts on Immunization in October 2016 (2).

ABBREVIATIONS AND ACRONYMS

CC	Certificate of containment
CCS	Containment Certification Scheme
CEN	European Committee for Standardization
CP	Certificate of participation
CWA	CEN Workshop Agreement
GAPIII	Global Action Plan III
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
ICC-NC	Interim certificate of containment-specific nonconformity
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 polio vaccine
PEF	Poliovirus-essential facility
VDPV	Vaccine-derived poliovirus
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

DEFINITIONS

Audit: The systematic, independent¹ 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 Containment Certification Scheme, the term “audit” may be applied to a gap assessment and/or interim certificate of containment/certificate of containment assessments.

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: The protection, control and accountability for biological agents and toxins within biological facilities to prevent their unauthorized access, loss, theft, misuse and diversion, or their intentional unauthorized release.

Certificate of containment (CC): A certificate that can only be awarded to poliovirus-essential facilities that hold a valid certificate of participation/ interim certificate of containment. A CC indicates that the poliovirus-essential facility has achieved full compliance with Annex 2 or 3 of GAPIII, as independently verified by the national authority for containment of the hosting country, in consultation with the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC). 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 GAPIII but has identified the outstanding gaps in compliance and has adequate interim measures in place as verified by the national authority for containment. Action must be taken to address the need for full conformity to GAPIII, or to prepare for the cessation of work to defined timescales. An ICC is awarded to a poliovirus-essential facility by the national

authority for containment of its hosting country, in consultation with the GCC. A GCC-endorsed ICC bears the signature of the GCC and a unique ICC number.

Certificate of participation (CP): A certificate that can only be awarded to facilities in countries that have demonstrated compliance with the required secondary and tertiary safeguards described in GAPIII. A CP indicates that the national authority for containment, in consultation with the GCC, has recognized a facility as a suitable candidate to become a poliovirus-essential facility. A CP formalizes the eligibility of the facility to engage in the GAPIII CCS process and its commitment to achieve an interim certificate of containment/ certificate of containment. A GCC-endorsed CP bears the signature of the GCC and a unique certificate of containment number.

Certification: The systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance.

Containment: A system for confining microorganisms, organisms or other entities within a defined space.

Facility: Any site (e.g. laboratory, repository or vaccine production unit) 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 as serving critical national or international functions that involve the handling and storage of needed poliovirus materials post-eradication under conditions set out in Annex 2 or 3 of GAPIII. According to GAPIII, facilities are required to hold a valid certificate to handle and store polioviruses beyond Phase I.

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 GAPIII requirements.

Global Certification Commission (GCC): The term commonly used to refer to the Global Commission for the Certification of the Eradication

¹ Independent from the organization being audited.

of Poliomyelitis, which has the responsibility to define the parameters and processes by which polio eradication is certified.

Guidelines: Principles or criteria guiding or directing action.

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.

Inspection: A conformity evaluation by observation and judgement, accompanied as appropriate by measuring, testing or gauging.

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

Interim certificate of containment-specific nonconformity (ICC-NC): Nonconformity that cannot be closed due to the need for major structural work or other similar reasons, thus preventing the issuance of a full certificate of containment. All outstanding ICC-NCs must be closed prior to the issuance of a certificate of containment. By definition, all ICC-NCs will be NC1s since they represent an absence of one or more required system elements.

National authority for containment (NAC): The national authority responsible for GAPIII containment certification. 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.

Safeguards, primary: Containment precautions

and stipulations designed to minimize the facility-associated poliovirus risk of exposing and/or infecting populations. Primary containment safeguards reduce the likelihood of accidental or malicious release of poliovirus from a poliovirus-essential facility and subsequent transmission to the population. Poliovirus-essential facilities are responsible for the identification, implementation and maintenance of effective primary safeguards.

Safeguards, secondary: The population immunity profile consistent with minimizing the consequence of a poliovirus release from a poliovirus-essential facility, consisting of a national routine childhood immunization policy and national population coverage in line with GAPIII. The country hosting the poliovirus-essential facility is responsible for the implementation of the secondary safeguards, a prerequisite for the containment certification of facilities retaining polioviruses as of Phase II of GAPIII.

Safeguards, tertiary: The sanitation and hygiene conditions (good personal, domestic and environmental hygiene standards and closed sewage systems with secondary or greater effluent treatment) that minimize the risk of re-establishing the circulation of highly transmissible wild poliovirus in the event of reintroduction. The country hosting the poliovirus-essential facility is responsible for the implementation of the tertiary safeguards, a prerequisite for the containment certification of facilities retaining wild poliovirus in Phase III.

Standard: A document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

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

1.

Introduction

This document, *GAPIII Containment Certification Scheme*, defines the recommended mechanism for certification associated with global confirmation of poliovirus containment within poliovirus-essential facilities (PEFs). The World Health Organization (WHO) Containment Certification Scheme (CCS) described here supplements the *WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use* (GAPIII) and poliovirus eradication timelines and requirements to minimize facility-associated poliovirus risk.

GAPIII requires that the primary safeguards of facility containment, secondary safeguards of population immunity, and tertiary safeguards of facility location and associated environmental controls be set in place to effectively control and minimize the risks of facility-associated poliovirus release after eradication. While the primary safeguards are controlled by the PEFs themselves, the secondary and tertiary safeguards are controlled by 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 secondary and tertiary safeguards, i.e. the required levels of population immunity together with facility location and environmental controls, are in place. While the appropriate implementation of secondary and tertiary safeguards is a prerequisite for containment certification against primary safeguards, the CCS addresses only the assessment of primary safeguards.

This document describes the containment certification requirements as applicable to GAPIII Annexes 2 and 3. Annex 2 describes post-eradication containment requirements applicable to facilities retaining wild poliovirus (WPV), which includes vaccine-derived poliovirus (VDPV) strains.

Annex 3 describes containment requirements applicable to facilities retaining oral polio vaccine (OPV)/Sabin viruses. As GAPIII does not require certification of the facilities implementing standards for the safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities (GAPIII Annex 6), the laboratories adopting these measures are not covered by the CCS.

Once polio is eradicated, 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 primary safeguards of containment. 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 certificate of containment 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 GCC's ability 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 GAPIII is being implemented adequately and consistently around the world. While countries may elect to adopt alternative mechanisms, the latter may not meet the CCS's requirements, and these alternative schemes will not be assessed on an individual basis for parity with the CCS. Any certificates issued under such arrangements will not receive GCC endorsement.

The ability to demonstrate that a NAC has adopted an agreed and approved mechanism may help stakeholders to assess the validity of national certificates. Although the impact of the certification scheme is not yet fully known, 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 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

GAPIII was developed by WHO to provide a modern, comprehensive, risk-based and practical framework to ensure organizations that will handle and/or store stocks of poliovirus after type-specific eradication will do so with due regard for biorisk management. A key GAPIII 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 unauthorized release of poliovirus post-eradication. Such facilities may include those that manage:

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

Annexes 2, 3 and 6 in GAPIII describe a biorisk management system approach based on 16 elements derived from CWA15793 – *Laboratory biorisk management* (2011) (3). The 16 elements address all areas associated with the design, operation and management of the facilities that will be responsible for ensuring that the risk of accidental or malicious release of poliovirus after type-specific eradication is minimized.

This document outlines the CCS, defining key roles, responsibilities and associated mechanisms for stakeholders relating to the 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 post-eradication legacy planning.

A fundamental principle of GAPIII 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 certification scheme's roll-out and implementation. It should be noted that such information and guidance are provided for reference only, neither indicating that the examples provided are the only tools that may be considered suitable, nor that they are necessarily all that is required to demonstrate compliance with GAPIII and/or the measures described in this document.

1.4 CCS OBJECTIVES

The objectives of the CCS are to:

1. identify and define the roles and responsibilities of the parties 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 GAPIII controls have been appropriately identified, implemented and monitored in accordance with timelines aligned with the eradication programme; 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 in nature to that used in other risk-based management system certification schemes (e.g. Occupational Health and Safety Assessment Series (OHSAS) 18001 (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 GAPIII 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 recognized good practice in biorisk management.

Although ownership for oversight and containment certification of PEFs rests with designated NACs and the GCC, 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 forms of storage of polioviruses, including vaccine stockpiles that must be kept for a number of 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 as part of the containment certification process.

1.6 ROLES AND RESPONSIBILITIES

Oversight mechanisms have been set in place to ensure poliovirus will be contained within PEFs.

The parties 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)
- World Health Organization (WHO).

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

Poliovirus-essential facility

The PEF:

1. establishes, implements and maintains a biorisk management system aligned with the requirements set out in GAPIII;
2. provides relevant parties (NAC, audit team members, GCC) 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
4. reports to the NAC and other relevant parties any event, change to processes or other issue that could jeopardize the status of a certificate under the CCS.

National authority for containment²

The NAC:

1. ensures and demonstrates that the required primary, secondary and tertiary safeguards described in GAPIII are met;
2. establishes national mechanisms aligned with the CCS to ensure PEFs are appropriately assessed and comply with GAPIII requirements;
3. reviews and processes applications for containment certification in consultation with the GCC, ensuring only relevant facilities enter the containment certification process;
4. ensures containment certification activities are conducted so as to provide adequate assurance that the requirements set out in GAPIII and the CCS are effectively implemented and maintained;
5. ensures effective procedures are established and maintained to address relevant aspects of the containment certification cycle, including:
 - application and acceptance
 - contract/agreement with the PEF applying for a certificate of containment (CC) or interim certificate of containment (ICC)

² 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.

- planning of audits
 - review of applications and other documents
 - initial and periodic audits
 - resolution of findings
 - certificate issuance
 - certificate maintenance
 - certificate renewal;
6. ensures effective procedures are established and maintained 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 (see the GAPIII Containment Certification Cost (Man-day) Calculation Guidance)
 - 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) with appropriate access to pertinent information required for containment certification activities;
 8. provides relevant parties (e.g. GCC) with appropriate access to pertinent information demonstrating that secondary and tertiary safeguard requirements are appropriately met;
 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*; and
 10. issues, suspends or revokes certificates of containment, in consultation with the GCC.

Global Commission for the Certification of the Eradication of Poliomyelitis

The GCC:

1. reviews applications to ensure that a designated PEF is eligible to join the certification process;
2. approves/endorsees the process to award containment certificates;
3. reviews and approves national reports on containment activities based upon information supplied through the GCC-endorsed process (following the CCS);
4. approves/endorsees the issuance of containment certificates (certificates of participation, interim certificates of containment and certificates of containment) submitted following the CCS process; and
5. 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;
3. provides coordination, implementation support, technical assistance and expert advice regarding the CCS to countries, NACs and the GCC; and
4. addresses feedback relating to the CCS.

1.7 DELEGATION OF ACTIVITIES

Conditions to outsource 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.

2.

Containment certification process

GAPIII requires PEFs handling and storing poliovirus in the post-eradication era to be located in countries that have demonstrated the appropriate implementation of required secondary and tertiary safeguards, and ultimately to achieve and maintain a full CC. However, it is also recognized that both NACs and PEFs will require time to fully implement GAPIII controls and/or cease work involving poliovirus materials to a defined timescale associated with eradication. The continuation of certain activities, until all three poliovirus types are declared eradicated (in Phase II of GAPIII), is also considered critical in ensuring the maintenance of vaccine supply, critical diagnostics, surveillance and research.

In addition, challenges will exist in adhering to agreed timelines for the poliovirus type 2 containment period (Phase II of GAPIII) as the CCS is rolled out. Thus, to manage the practical challenges associated with the implementation of full containment for PEFs during this interim period, a CP and an ICC have been introduced as part of the certification scheme. 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 accommodating the need for the required flexibility during the endgame period³ of polio eradication.

A CP and/or ICC may therefore be awarded in Phase II of GAPIII, but PEFs retaining WPV/VDPV in Phase IIIa or OPV/Sabin polioviruses in Phase IIIb of GAPIII are expected only to hold a valid CC. Only in exceptional circumstances, and with the agreement of the relevant NAC and the GCC, will the issuance and/or maintenance of an ICC be permissible in Phase III under the CCS.

The process for containment certification against GAPIII 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 certification process during the poliovirus type 2 containment period.⁴ The process for the issuance of an ICC and a CC is similar and depends partly on whether an ICC is achieved as a preceding step to the award of a full CC, in which case differences primarily relate to the need for specific risk assessments addressing areas of nonconformity as facilities prepare to achieve CC status.

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

2.1 CERTIFICATE OF PARTICIPATION

The issuance of a CP initiates the certification process and formally engages a designated PEF 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 in consultation with the GCC, to demonstrate that they have been accepted as eligible applicants to enter the containment certification process.

On condition that the facility-hosting country has presented evidence of appropriate implementation of secondary and tertiary 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,

³ World Health Organization. Polio Eradication & Endgame Strategic Plan 2013-2018. Geneva: WHO; 2013.

⁴ No CP will be issued beyond the date of full eradication of all polioviruses.

and is considered to have accepted the need to comply with GAPIII 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; in such cases it is agreed that the CP will subsequently be revoked and no CC/ICC will be issued.

2. An application for a CP is submitted by the candidate facility to the NAC (see the GAPIII Containment Certification [Application Form](#)), detailing:
 - a. the certificate ultimately being sought (CP/ICC/CC);
 - b. the need/rationale for retaining poliovirus materials after eradication, subject to containment through the initial period prior to the issuance of an ICC/CC, including 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; and
 - c. an outline of a time-bound action plan specifying the proposed measures to achieve ICC/CC status or cease work with poliovirus.
3. Within 20 working days of its receipt, the NAC is encouraged to review the application, in consultation with other relevant authorities, to ensure the facility is potentially capable of meeting the criteria for a PEF in relation to GAPIII. The NAC then submits satisfactory applications to the GCC for review, including an overview of any proposed evaluation and monitoring activities, designed to ensure work relating to the CP will be conducted appropriately.
4. The GCC reviews the application and makes recommendations to the NAC within 30 working days. Should the application be considered unsatisfactory, 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. Provided no

significant objections are raised, approval will be granted that the applicant PEF can enter the CCS process through the issuance of a CP. If the application is rejected by the GCC, the applicant can choose to resubmit, providing additional information is made available via the NAC that substantially alters the nature of the original application.

5. 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, with copy to the GCC.
6. 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; and
 - b. an ability to continue work under stipulated conditions, together with any specific restrictions.
7. The validity of a CP is time-bound and limited to a maximum period of one year, during which CP-holding facilities are expected to be awarded an ICC/CC or cease work with poliovirus. Should additional time be required, an application for extension of the CP must be made to the NAC at least one month prior to the expiry of the CP, with the extension limited to a maximum of two three-month periods. In such instances, the PEF must demonstrate legitimate and extenuating circumstances to the NAC and the GCC.

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 INTERIM CERTIFICATE OF CONTAINMENT

An ICC will be issued to a CP-holding PEF that is assessed as broadly compliant against Annex 2 or 3 of GAPIII by its respective NAC in consultation with the GCC but that cannot meet all the requirements during the poliovirus type 2 containment period. However, these facilities will have demonstrated that adequate alternative control measures are in place for work with poliovirus while action is taken to address the need for full conformity or to cease work to a defined timescale. This may include facilities that require short-term approval while alternative arrangements for more permanent conditions are finalized, together with those wishing to hold poliovirus materials within secure repositories while facility upgrades are being conducted, or during pauses in work with poliovirus. Such

repositories will need to meet the requirements set out in GAPIII, although certain exclusions may apply due to the nature of the activities being performed (e.g. virus only being held under secure storage conditions with no manipulation).

Although an ICC does not infer full conformity to GAPIII requirements, it is emphasized that this in no way indicates an increased tolerance for risk relating to facilities storing and handling polioviruses after type-specific eradication. 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.

An ICC is issued provided the following conditions are met:

Initiation and planning

1. Within 60 days of the award of a CP, the NAC is encouraged to formally engage the PEF in the ICC process by establishing a contract/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; and
 - f. the health, safety and welfare of the audit team throughout the containment certification process (a declaration will be included to that effect).
2. Once the contract/agreement is signed, the NAC can start planning for the initial full-scope audit against Annex 2 or 3 of GAPIII. 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, particular 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 an international team, where applicable, 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. In the event that NCs are identified before (or during) the initial audit that cannot be fully addressed prior to the issuance of the CC (e.g. the need to install an exit shower arrangement), 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.⁵

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.⁶ Within 10-20 days of the audit, an audit report detailing any NCs is encouraged to 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, together with at least one ICC-NC.⁷
2. Within 40 days of receipt of the report, the PEF is encouraged to develop an action plan detailing how all identified NCs will be closed (see the GAPIII Containment Certification [Audit Findings and Corrective Action Plan](#)). The action plan will detail the root causes, corrective actions and dates by which the NCs are to be addressed. ICC-NCs will be closed to appropriate time frames that may extend

⁵ 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.

⁶ Detailed descriptions relating to audit teams, plans, schedules and on-site activities are provided in sections 3 and 4 below.

⁷ An NC that cannot be closed due to the need for major structural work or for other similar reasons, thus preventing the issuance of a full CC, is termed an ICC-NC (see section 4.6). By definition, all ICC-NCs will be NC1s since they represent an absence of one or more required system elements.

beyond those set for closure of standard NC1s and NC2s (see section 4.6).

3. Once the facility has completed the Audit Findings and Corrective 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.

Review and approval

1. Upon satisfactory completion of the ICC initial audit and approval of the PEF's action plan by the NAC (including the NAC's review of the overall conduct of the audit), the NAC submits all relevant documents to the GCC for review. Submitted documentation will include the ICC initial Audit Report, incorporating the list of identified ICC-NCs/NCs and time-bound action plan, together with risk assessments and any other supporting documents, and a recommendation regarding the award of the ICC.
2. The GCC then reviews the information and provides feedback to the NAC on the award of the ICC within 60 working days, during which time further consultations may take place if required. Should the report be considered unsatisfactory, 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.
3. The NAC communicates the final outcome of the audit to the PEF within five working days of receipt of the GCC's recommendations.

Monitoring and renewal

1. The NAC monitors progress on the agreed improvement 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. If the improvement 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 limited to a maximum period of three years. An ICC-holding PEF is expected to achieve a full CC within this time frame, although, if more time is required, an application for extension can be made to the NAC at least three months before the expiry of the ICC. Any extension

period of the ICC is limited to a maximum of an additional 12-month period; only under exceptional circumstances will a request be approved to extend the ICC for a further period, not exceeding a further 12 months. In such instances, the PEF must submit a request to the GCC via the NAC, demonstrating the legitimacy of such a request and detailing the extenuating circumstances.

3. Unless otherwise stated (i.e. should the duration be less than three years), an ICC has a validity of three years from the date of issuance. The certificate is issued following the successful completion of the initial full-scope certification audit against all 16 elements specified in Annex 2 or 3 of GAPIII, followed by periodic audits conducted in the second and third years, 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.

2.3 CERTIFICATE OF CONTAINMENT

A CC can be issued directly following the award of a CP, or alternatively as an upgrade to an ICC,⁸ once the PEF presents evidence to the NAC in consultation with the GCC that all GAPIII requirements have been met. If the ICC is upgraded to a CC during the three-year period covered by the ICC, the certification cycle remains unchanged (i.e. it is upgraded to CC within an ongoing three-year cycle).

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.
2. 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 ICC-NCs in place. This may require a reduced-scope audit with a smaller, more specialized team where appropriate. The GCC shall be consulted in terms of the measures that will be taken to close any ICC-NCs following the same process as for issuance of an ICC, i.e. the NAC will present evidence to the GCC that all existing NC1s

⁸ All outstanding ICC-NCs must be closed prior to the issuance of a CC.

have been satisfactorily closed and will make a recommendation as to whether to proceed to full CC status.

3. A CC is valid for three years, part of which may encompass the upgrade of the certificate from ICC to CC where relevant.
4. A CC full-scope audit is repeated at the end of the three-year cycle, where successful completion will result in renewal of the CC for a further three years. A CC confirms that the facility is compliant with all requirements set out in GAPIII 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.

2.4 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.

2.5 MODIFICATION, SUSPENSION, WITHDRAWAL, COMPLAINTS AND APPEALS

The CP/ICC/CC may be withdrawn if the PEF fails to comply with GAPIII requirements. In such cases, the NAC should warn the facility⁹ 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.

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

1. violation of the terms stipulated in the containment certification contract/agreement, including:
 - non-payment of fees;
 - failure to allow 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 GAPIII and/or of associated containment certification requirements, including:
 - failure to identify and implement adequate control 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 in exceptional circumstances, provided the NAC is kept fully informed of all correspondence. It is at the discretion of the GCC 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, but ultimately rests with the NAC.

⁹ The communication should be addressed to the facility focal point identified on the GAPIII Containment Certification [Application Form](#) used to initiate the certification process.

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. 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 a number of specialist areas, including but not necessarily limited to:

1. poliovirus biology;
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. GAPIII 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 GAPIII 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 GAPIII 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'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 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 the required qualification requirements for auditors 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 speciality 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.

Translator¹⁰ 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

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

- education and work experience
- auditing experience and CCS training
- personal attributes.

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

3.4 EDUCATION AND WORK EXPERIENCE

A CCS auditor should have relevant tertiary education, preferably an ordinary/first degree (e.g. BSc, BEng or equivalent) or higher degree (e.g. MSc, PhD or equivalent). In addition, an auditor should show appropriate specific training/competence (e.g. safety management system auditing), work experience 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.

¹⁰ The term "translator" is used to include interpretation skills.

A CCS auditor should demonstrate appropriate knowledge of industry 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 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 applicants should have a minimum of five 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 required knowledge and roles of the audit team. Candidates must justify relevant work experience based on a combination of the following criteria:

Safety management systems

Candidates must:

- a. have formal tertiary education;¹¹
- b. have formal qualification¹² 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 five years.

Biorisk management

Candidates must:

- a. have formal qualifications in biorisk

¹¹ 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.

¹² 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.

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

Engineering principles and concepts

Candidates must:

- a. have formal tertiary education¹³ 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 five years.

¹³ 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.

Emergency preparedness

Candidates must:

- a. have formal tertiary education¹³ 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 five years.

Security

Candidates must:

- a. have formal tertiary education¹³ 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 five years.

3.5 AUDITING EXPERIENCE AND CCS TRAINING

Auditor

Auditors must demonstrate audit experience encompassing the entire audit process conducted against all 16 GAPIII elements, with formal approval of competence as an auditor under a qualified audit team leader in the same discipline (engineering controls, vaccine production, etc.).

Particularly in the early stages of the CCS, issues related to sourcing appropriate numbers of suitably qualified auditors will most likely be experienced, and practical solutions will need to be found to overcome these challenges. Some highly qualified candidates may not meet all of the requirements but may otherwise be deemed highly suitable. These individuals may also participate in the role of technical experts, which may contribute to gaining the required additional experience to achieve auditor status.

However, to ensure that a satisfactory audit can be performed, previous auditing experience is considered necessary and no exceptions will be made for lead auditor and auditor grades not meeting the minimum requirements. As part of the qualification process, an auditor monitoring report (see the GAPIII Containment Certification [Auditor Monitoring Report](#)) should be produced by a qualified lead auditor responsible for candidates seeking qualification. Records of national auditor competencies should be reviewed and maintained by the NAC and made accessible to the GCC.

An individual can qualify as an auditor by completing a minimum of 10 equivalent days of GAPIII auditing as a trainee, spread across a minimum of three audits, with a qualified auditor or lead auditor acting in the capacity of trainer/verifier. At least one audit should be a full-scope audit (initial or recertification audit) encompassing all 16 elements (as opposed to gap assessments, or periodic audits of more limited scope).

To maintain status as a CCS auditor under GAPIII, auditors should take part in a minimum of five GAPIII audits completed in the previous three years,¹⁴ with at least one in which full participation in planning and reporting activities took place.

Lead auditor

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

- a. demonstrate competence in effective leadership and efficient management of CCS audits, including all aspects of planning, execution, reporting and required leadership and communication skills;
- b. have successfully performed the required number and type of audits in the role of acting lead auditor (see section 3.2) with a competent lead auditor acting as mentor and assessor; and

¹³ 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.

¹⁴ 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 GAPIII audits is subject to approval by the NAC on a case-by-case basis.

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

A lead auditor may be deemed qualified after completing two full-scope GAPIII audits (minimum three days' duration) acting in the role of a lead auditor under the guidance of a qualified lead auditor or team leader. Specific competence should be demonstrated in relevant activities, including conducting opening and closing meetings, categorizing and presenting findings, and communicating with facility management and other relevant stakeholders.

To maintain status as a CCS lead auditor under GAPIII, lead auditors should take part in a minimum of five GAPIII audits completed in the previous three years,¹⁵ and in at least two act in the role of team leader, with at least one being a full-scope initial or recertification audit.

CCS auditor training requirements

To qualify for their first CCS assignment, all CCS auditors must successfully complete both components of the classroom course, *GAPIII Training for Auditors*:

1. GAPIII auditor requirements (minimum three days' duration); and
2. relevant management system auditing training (minimum two days' duration) (e.g. ISO 9001 (7) and OHSAS 18001 (4)).

Auditors already qualified in management system auditing (e.g. ISO 9001 (7), OHSAS 18001 (4) or other internationally recognized management system standards) must complete the classroom training:

1. GAPIII auditor requirements (minimum three days' duration).

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;

¹⁵ Countries that will experience limitations in terms of numbers of PEFs and in the ability to qualify/maintain the qualification of lead auditors may wish to consider maintaining competence through involvement in other similar activities (e.g. relevant containment-related and/or Good Manufacturing Practice inspections). Lead auditors who fall into this category could also be subject to approval on a case-by-case basis.

- **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 completed 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 in a structured and documented manner, with the creation and maintenance of appropriate profiles and records.^{16, 17} They may mainly be assessed by interview, feedback from witnessing auditors during auditing training, and feedback from facility personnel or others associated with the performance of the audit.

3.7 AUDITOR QUALIFICATION AND REQUALIFICATION

CCS auditor application¹⁸

Candidates wishing to be considered for qualification should submit the relevant auditor or lead auditor application to their NAC, or to WHO in countries where a NAC is not available (see the GAPIII Containment Certification [Auditor Application Form](#)). The submission should at least include updated curriculum vitae, copies of relevant qualifications including training records, and a completed GAPIII containment certification auditor log (see the GAPIII Containment Certification

¹⁶ 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.

¹⁷ This is described in Annex D of ISO 17021-1:2015 (5).

¹⁸ 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.

Auditor Log). The NAC should review and approve applications and maintain a register of qualified auditors, trainers and technical experts. It may use the GAPIII Containment Certification Register of GAPIII Auditors, Technical Experts and Trainers form.

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, 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;

- 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 GAPIII TRAINING FOR AUDITORS

Trainers appointed to provide *GAPIII Training for Auditors* courses should be qualified as CCS lead auditors. Applicants are expected to witness one course, co-present one course and fully present one course under the guidance and approval of a qualified GAPIII trainer for that course before they can be qualified as GAPIII trainers for auditors. The qualified GAPIII trainer for auditors should be an internationally recognized provider of training and/or have completed an appropriate train-the-trainer course. WHO will review and maintain a list of qualified trainers.

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, who should in turn conduct national calibration meetings with all relevant personnel (e.g. lead auditors, auditors, observers).

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 GAPIII audits in keeping with the CCS.

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 CP-holding PEF 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.

The audit team will 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 qualified auditor. The team should also include locally qualified auditors and/or technical experts who are aware of local laws, regulations and practices. Audit teams should be nominated by the NAC, involving suitably qualified personnel listed as approved auditors and technical experts (see the GAPIII Containment Certification [Register of GAPIII Auditors, Technical Experts and Trainers form](#)).

4.2 AUDIT PLANNING

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

at the country level:

- documented evidence that secondary and tertiary safeguards, as described in GAPIII, are met; and
- at the facility level:

- copy of the containment certification contract/agreement between the NAC and the facility;
- the GAPIII containment certification application form (see the GAPIII Containment Certification [Application Form](#));
- requested documents (see the GAPIII Containment Certification [Document Request Form](#));
- any reported changes to the scope of certification, if applicable;
- previous audit reports and lists of findings, if applicable; and
- previous corrective 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 audit team members;
- provide the Audit Plan; and
- discuss a possible audio- or videotaping 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 in agreement with the facility. Unless otherwise agreed, the facility is advised to submit all requested documents (see the GAPIII Containment Certification [Document Request Form](#)) to the team leader at least 20 days before the audit.

The team leader is responsible for preparing the Audit Plan (see the GAPIII Containment Certification [Sample Audit Plan](#)) and for assigning

responsibility for specific areas or elements of GAPIII 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.

4.3 INFORMATION REQUIREMENTS

A typical list of documents for review¹⁹ (see the GAPIII Containment Certification [Document Review Register](#)) at the beginning of the audit is shown below, with ideally one copy distributed to each auditor unless delivered electronically. Those in italics should be received ahead of the initial full certification audit. The documents should include:

- *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 16 elements within GAPIII;
- 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 GAPIII Containment Certification [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

¹⁹ Before any documents are shared, all security requirements for the transport, transfer and handling of sensitive information must be met.

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 GAPIII 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 in light of 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 advisers, translators nor observers should assume the role of consultant. Where suitable, however, appropriate individuals (e.g. auditors, technical advisers) may educate the facility staff on aspects of GAPIII 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 adviser or observer should attend an audit if they have worked in a 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 contract/agreement with the facility.

Audited documents

The team leader should appoint a member of the team to maintain a register of documents provided by the facility (see the GAPIII Containment Certification [Document Review Register](#)) 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 GAPIII 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 fulfil requirements under GAPIII. NCs (deficient practices) 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 GAPIII clause, 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 GAPIII Containment Certification [Audit Report Template](#)).

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 GAPIII.

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 doubt that controls will meet the requirements. In this case the judgement can be that, despite the issues identified, the overall system requirement is defined, implemented and effective.

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 GAPIII 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.

Nonconformities under an ICC (ICC-NC)

By definition, under an ICC, NCs against GAPIII requirements will exist – hence the rationale for not proceeding directly to the application for or award of a CC. These NCs should be categorized as ICC-NCs, and will be NC1s since they represent an absence of one or more required system elements, and should follow the assessment review and closure mechanisms described in section 2, avoiding the need for closure of NCs as described for the issuance of a CC in section 4.7.

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 violation against the given requirement.

The closing meeting may be audio- or videotaped at the discretion of the team leader. In these cases, the team leader must obtain a copy of the tape 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 GAPIII Containment Certification [Audit Report Template](#)). 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 should contain at least the following information:

- documented evidence that the required secondary and tertiary safeguards described in GAPIII are met;
- details of the facility assessed, including any modifications in the scope of the audit from the original application;
- the composition of the audit team and a list of the key facility contacts;
- a brief, bulleted summary of the key issues and noteworthy efforts, as well as the NCs and observations that address the assessed primary safeguards;
- a summary table showing the number, types and categories of findings;
- a summary stating the overall conclusions and next steps, including associated timelines; and
- other relevant information as appropriate.

The action plan should contain at least the following information:

- 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
- root-cause analysis relating to the NCs
- proposed actions to close the NCs
- dates on which the actions should be initiated and completed
- date corrective action is accepted in principle
- name of the person responsible for acceptance
- verification activity
- name of the person responsible for the verification

- dates on which each individual finding will be closed
- auditor's notes.

Time to prepare the report should be incorporated into the audit plan. Ideally, the report should be completed on-site while the audit team is together. If this is not possible, 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. 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 action plan (see the GAPIII Containment Certification [Audit Findings and Corrective Action Plan](#)) should be submitted to the facility with the sections on the number and type of NCs/observations completed by the team leader. The facility should then update the 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 Action Plan.

Once the facility has completed the Audit Findings and Corrective 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.

When agreement has been reached regarding the required corrective actions, the time frames for completion are as follows:

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 submitted within 90 calendar days, including 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.

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). A corrective action plan must be submitted within 90 calendar days, including 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.

In verifying the potential effectiveness of the proposed corrective actions, the team leader should consider the likely effectiveness of the root-cause analysis and the evidence presented on the proposed actions. No certificate should be issued until the NC1s have been verified as being effectively closed and/or an agreed plan is in place for the closure of the NC2s. Should a follow-up visit be required to witness the closure of the NCs, a 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.

Ineffective corrective action

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

NC1 – 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.

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 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, 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 Action Plan; and
- the recommendation from the team leader/NAC regarding the award of the ICC/CC.

The GCC 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 GAPIII 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 major NCs were closed and a written commitment for timely corrective action was received from the facility for all minor NCs.

After the review, the GCC will generate a report to the NAC approving or rejecting the issuance of the ICC/CC.

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.

6. CCS feedback and review

Feedback on the CCS will be collected by WHO and the GCC. As part of the activity, the CCS feedback form (see the GAPIII Containment Certification [Feedback Form](#)) should be completed by the facilities, NACs and audit team members engaged in the containment certification process, and similar information gathered from other relevant parties. This information should be collected as part of a documented review of the programme and its effectiveness, including how the goals and objectives of the CCS are being met. Summary statistics of containment certification activity, together with recommendations for any amendments to the CCS or its operation, will be part of a continuous improvement process.

The GCC should regularly review the performance of the CCS. The review input should include:

- the satisfaction survey results
- any complaints received
- the auditor's performance and feedback
- resource issues
- compliance with CCS requirements.

The results of the review should be shared with stakeholders.

A full review of the CCS and associated processes will be conducted on a three-yearly basis, unless a more frequent review is warranted. At that time, a consultation exercise may be conducted with relevant stakeholders, including PEFs, audit team members, NACs and the GCC.

7.

Sample templates

The following GAPIII 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. Cost (Man-day) Calculation Guidance
2. Application Form
3. Audit Findings and Corrective Action Plan (CAP)
4. Auditor Monitoring Report
5. Auditor Application Form
6. Auditor Log
7. Register of GAPIII Auditors, Technical Experts and Trainers
8. Document Request Form
9. Sample Audit Plan
10. Document Review Register
11. Audit Attendance Sheet
12. Audit Report Template
13. CCS Feedback Form

References

1. World Health Organization. WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use. Geneva: World Health Organization; 2014.
2. World Health Organization. Meeting of the Strategic Advisory Group of Experts on immunization, October 2016 – conclusions and recommendations. *Wkly Epidemiol Rec.* 2016;91:567-9.
3. European Committee for Standardization (CEN). CEN Workshop Agreement CWA15793 – Laboratory biorisk management. Brussels: CEN; 2011.
4. Occupational Health and Safety Assessment Series (OHSAS). Occupational health and safety management systems – Requirements. 18001:2007. London: OHSAS Project Group; 2007.
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.
6. International Organization for Standardization/International Electrotechnical Commission (ISO/IEC). Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. 17011:2004. Geneva: ISO/IEC; 2004.
7. International Organization for Standardization (ISO). Quality management systems. 9001:2015. Geneva: ISO; 2015.



**World Health
Organization**

Avenue Appia 20
1211 Geneva
Switzerland

ISBN 978-9-24-151147-6



9 789241 511476