

GAPIII AUDITOR QUALIFICATION AND AUDIT SUPPORT PLAN 2021–2023

GAPIII auditor qualification and audit support plan 2021–2023.

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ABBREVIATIONS AND ACRONYMS

AAT	Advanced auditor training
AQAS	Auditor qualification and audit support
CC	Certificate of containment
CCS	GAPIII Containment Certification Scheme
CEV	Country engagement visit
COVID-19	Coronavirus disease that emerged in 2019
CP	Certificate of participation (in the containment certification process)
GAPIII	Global Action Plan III for Poliovirus Containment
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
NAC	National authority for containment
PEF	Poliovirus-essential facility
TS	Technical support
WHO	World Health Organization

AIM

This document sets out an auditor qualification and audit support (AQAS) plan to provide a sustainable series of activities relating to the qualification of auditors and the certification of poliovirus-essential facilities (PEFs) and associated WHO-related technical support (TS) over the 2021 to 2023 period. The plan also aims to ensure key activities can proceed in support of the extension of the expiration of certificates of participation (CPs) to April 2022 by the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC). In addition, it makes provision for the remote delivery of activities during the period in which travel restrictions are likely to make onsite delivery problematic due to COVID-19 restrictions.

BACKGROUND/RATIONALE

Significant progress has been made on a number of containment-related activities, including the establishment of 22 of 24 national authorities for containment (NACs), the issuance of CPs to 32 of 73 candidate PEFs and the training of 252 candidate GAPIII Containment Certification Scheme¹ (CCS) auditors from every WHO region. However, it is also important to note that the WHO Global Action Plan III for Poliovirus Containment² (GAPIII) was published in 2015 and as of December 2020 no interim or full certificates of containment (ICC or CC, respectively) have been issued.

The reasons for the certification-related challenges are complex and vary between different NACs. It is increasingly clear, however, that several key factors need to be addressed through a TS programme so required progress can be made according to what are considered reasonable and necessary timelines, including:

1. further clarity in relation to the required actions and timelines for certification and the maintenance of GAPIII CCS certificates;
2. the formal engagement of individual NACs and their PEFs to ensure delivery of the certification programme;
3. the provision of a structured and sufficiently flexible series of TS packages to provide the support NACs require, together with clear time-bound expectations on all parties; and
4. the development of long-term in-country capacity and capability to ensure the responsibility for certification activity rests with the respective NACs, hence allowing the Global Polio Eradication Initiative (GPEI) to reduce levels of TS and refocus priorities once the containment certification of all PEFs has been achieved.

Consideration of these factors has led to the development of this AQAS, designed to align with the *Polio Endgame Strategy 2019–2023: Eradication, integration, certification and containment*³ in both content and timing. The development and implementation of such a plan are considered essential to maintain the momentum already achieved and to ensure hard deadlines can be set and formal commitments made to guarantee all PEFs are either certified by the end of 2023 or alternative solutions are agreed for any

¹ See Global Polio Eradication Initiative. Containment Guidance and Tools, GAPIII and Containment Certification Scheme. Geneva: World Health Organization; 2020 (<http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources>, accessed 17 December 2020).

² 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). Geneva: World Health Organization; 2015 (http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf, accessed 17 December 2020).

³ Global Polio Eradication Initiative. Polio Endgame Strategy 2019–2023: Eradication integration, certification and containment. Geneva: World Health Organization; 2019 (<http://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf>, accessed 17 December 2020).

NACs/PEFs unwilling/unable to achieve GAPIII certification by that time. This is highlighted since it would clearly be a major achievement for the GPEI and global eradication programme if all PEFs were certified by the end of the current endgame strategy.

INTERIM MEASURES DUE TO COVID-19 TRAVEL RESTRICTIONS

As of late 2020, the international COVID-19 outbreak continues to restrict international travel. Despite this situation, the GCC expects NACs and PEFs to continue to demonstrate progress towards achieving containment certification. For this reason, alternative measures and approaches are described in specific sections of the plan to allow essential activities to continue during this challenging period.

At present, all proposed activities including country engagement visits (CEVs), training, auditor qualification activities and gap assessments/certification audits will be conducted remotely, even if this poses challenges for NACs, audit teams, PEFs and WHO. Should restrictions be relaxed, making travel feasible again, the plan may need to be adjusted accordingly.

The following principles are therefore recommended regarding the provision of remote TS during this period:

1. Onsite activities remain the preferred option and remote activities will only be conducted as an interim measure for as long as deemed necessary given the prevailing COVID-19 situation.
2. While WHO will make all reasonable efforts to ensure the remote activities are fit for purpose, these cannot entirely replace the need for onsite observations of actual situations. Although the intention is to go ahead with all types of activity described in the plan, some areas (e.g. inspections of facilities, auditor performance evaluations during tours, etc.) will not be feasible during this period. The objective will therefore be to complete these activities remotely insofar as this is reasonably possible. The precise nature of any auditor qualification or PEF certification activity and associated follow-up after the end of COVID-19 restrictions will be agreed on a case-by-case basis, influenced by experience gained during remote activities conducted to that date.
3. The GCC expects that all CP-holding facilities will have engaged in meaningful assessment activities and demonstrated adequate levels of control over their contained polioviruses prior to the end of April 2022. Further extensions of CPs or alternative arrangements will therefore be dependent on the implementation of agreed measures as per country engagement activities and associated plans.

AQAS TECHNICAL SUPPORT

As the bodies responsible for oversight of GAPIII-related certification activities, NACs are required to conduct certification audits as defined by the CCS. However, the provision of auditors to conduct these activities offers certain associated challenges, not least because this is a new scheme that requires training, experience and the qualification of auditors as part of the development and implementation of the certification mechanism managed by the NAC. As such, WHO has been working with partners to devise TS packages to facilitate the auditor qualification and/or auditing process in countries.

A range of approaches to TS is therefore presented, based on four broad and potentially flexible packages. Criteria in assigning countries to packages will be assessed on a case-by-case basis and include eradication programme considerations, required timelines, country readiness, current/planned poliovirus work programmes and the number of PEFs, together with how long-term auditor qualification and certification activity will be managed in-country.

Although some reallocation of countries to different packages may be needed, an initial list is shown in Table 1.

Table 1. Country categorization

Package 1: Country engagement visit + advanced auditor training + WHO-led auditor qualification for two auditors (one lead auditor and one auditor) over a minimum of two full-scope audits.	
Regional Office for the Americas	Canada
	USA
Regional Office for Europe	Belgium
	Denmark
	France
	United Kingdom
Package 2: Country engagement visit + advanced auditor training + WHO-led auditor qualification for two auditors (one lead auditor and one auditor) over a minimum of five full-scope audits.	
Regional Office for Europe	Russian Federation
Regional Office for South-East Asia	India
Regional Office for the Western Pacific	China
	Japan
Package 3: Country engagement visit + national authority for containment training on outsourcing audits + one WHO-led initial certification audit.	
Regional Office for Africa	South Africa
Regional Office for the Americas	Cuba
Regional Office for the Eastern Mediterranean	Iran (Islamic Republic of)
	Pakistan
Regional Office for Europe	Belarus
	Hungary
	Romania
	Serbia
	Sweden
Regional Office for South-East Asia	Indonesia
Regional Office for the Western Pacific	Australia
	Republic of Korea
	Viet Nam
Package 4: Country engagement visit + advanced auditor training.	
Regional Office for Europe	Netherlands

SUPPORT PACKAGES

The various support packages are described below. It is emphasized that they will be implemented concurrently, for example some Package 3 activities may be completed before those in Packages 1 and 2.

Although a broad overview of activities is presented below, the precise delivery mechanisms will be detailed in customized tactical plans agreed in consultation with the individual NACs during the CEV.

Under the AQAS, WHO will provide support in three main areas:

1. Country engagement visit (CEV)
2. Advanced auditor training (AAT) or NAC training on outsourcing audits
3. Auditor qualification and audit support

Country engagement visit (CEV)

This activity will be carried out for all PEF-hosting countries in a similar manner, resulting in an agreement between the parties to be used as the basis for the planning and delivery of the subsequent TS. The key objectives of the CEV are to:

1. clarify and establish WHO and NAC expectations in relation to the CCS/AQAS planning and implementation process;
2. understand the NAC's containment certification programme;
3. confirm the schedule of subsequent TS activities;
4. determine the readiness and commitment of the NAC and PEF(s) to proceed to the next stages of the TS (e.g. AAT, training on outsourcing audits, auditor qualification audits, facility certification audits); and
5. agree on a time-bound action plan, resources and financial provisions for the implementation of the selected TS package, including the prioritization of PEFs for certification audits.

Since a major component of the CEV is to work with the NAC to plan an audit schedule, the list of PEFs to be subject to certification must be available, together with a prioritization and confirmation of readiness.⁴ The CEV is therefore critical both to ensure alignment of WHO/NAC expectations and to agree on the subsequent qualification/certification model and schedule, allowing activities to proceed to defined timescales that can be suitably resourced and otherwise supported by all parties.

COVID-19 interim measures – Country engagement visit

CEVs will be carried out remotely (e.g. through tele-/videoconferencing, web meetings, etc.) and/or via other agreed means of communication until the travel situation improves.

Further arrangements relating to agendas, communication media, the selection of participants and other details will be discussed and agreed on prior to the CEV.

Advanced auditor training (AAT) or NAC training on outsourcing audits

AAT

AAT will be provided to countries associated with Packages 1, 2 and 4. The training will be provided by a WHO team consisting of one trainer/lead auditor and additional demonstrators/interviewees. One WHO staff member will also be present to act as a focal point for discussions with the NAC. All training materials will be provided and will include samples of the PEF management systems documentation, together with associated information needed to complete the simulated audit-related activities.

⁴ For the subsequent PEF certification/auditor qualification activity to proceed, PEFs must be available and ready within a suitable time frame, which may include the need for the NAC to first conduct initial visits/gap assessments.

Each AAT will focus on one candidate lead auditor and one candidate auditor. Additional audit team members can also attend the training as observers, technical experts and/or other roles deemed suitable by the NAC. However, it is emphasized that the training itself will be directed only towards the two candidates. The NAC will be responsible for the management of the wider team attending the training.

NAC training on outsourcing audits

This training will be provided for NACs of Package 3 countries. It will focus on their role and responsibilities regarding the conduct of GAPIII audits following CCS and interactions with external audit teams. Details of the training and any required NAC preparation activities will be discussed in advance of the activity.

COVID-19 interim measures – WHO-supported training courses

AAT, NAC training on outsourcing audits and other WHO-supported training courses (e.g. GAPIII awareness training, CCS training for auditors) will be provided online until the travel situation improves.

Further arrangements relating to training dates, schedules, communication media, the selection of participants and other course details will be discussed and agreed on with NACs ahead of the training.

Auditor qualification and audit support

Responsibility for auditor qualification and PEF certification

It is emphasized that under each package described below, the NAC will remain entirely responsible for all aspects of the certification activity and the issuance of GAPIII containment certificates as per CCS requirements.

Auditor qualification – Packages 1, 2 and 4

Package 1, 2 and 4 countries have enough PEFs to achieve and maintain in-country auditor qualification. For candidate auditors to be considered suitable to attend the AAT and progress through the qualification process, the following criteria must be met:

1. All CCS eligibility requirements must apply to the candidate auditors in relation to education, experience, sector knowledge, etc.
2. To be recognized by the GCC, candidates must demonstrate they have successfully completed the WHO GAPIII CCS Training for Auditors and passed the associated examination as per the CCS.
3. Auditor candidates must have submitted the completed auditor application form⁵ to their NAC for approval, with copies provided to WHO prior to confirmation of the qualification activity.

Package 1 countries are those deemed at the present time to have existing in-country audit capability similar in nature to that required under the CCS, and for which the expectation is that auditors may achieve qualification to a condensed timescale (estimated at a minimum of two full-scope audits). Auditor qualification audits in Package 1 will be WHO-assessed, allowing candidate auditors to demonstrate their capability to run GAPIII audits. During these auditor qualification activities, the WHO-appointed assessment team will not interact with the PEF or be otherwise involved in the running and conduct of

⁵ Global Polio Eradication Initiative. Containment Guidance and Tools, GAPIII and Containment Certification Scheme. Geneva: World Health Organization; 2020 (<http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources>, accessed 18 December 2020).

the audit. Two in-country auditors will undergo qualification with one as lead auditor. Once deemed qualified, the auditors can then proceed with subsequent completion of the national audit programme and the qualification of additional in-country auditors in line with the CCS, independently of WHO support.

Package 2 countries are those deemed at the present time not to have in-country audit mechanisms sufficiently similar to those described under the CCS and/or are subject to additional challenges in qualification (e.g. the need for significant translation during audit-related activities). Technical support for Package 2 countries will be similar to that under Package 1, but with a more hands-on approach by the WHO-appointed audit team during the early audits, allowing for the more gradual transition of activities to the in-country team. The number of audits for Package 2 countries is aligned with the CCS requirement of a minimum of five. During these auditor qualification activities, the WHO-appointed assessment team will not interact with the PEF or be otherwise involved in the running and conduct of a minimum of two audits (as per Package 1).

Package 4 countries are those that are developing their own in-country capacity under the CCS and have indicated they do not require extensive TS for auditor qualification, although some provision will be made available in terms of training (AAT) and wider engagement activities (e.g. the CEV). Package 4 countries will follow the CCS; how this will be done will be discussed during the CEV.

COVID-19 interim measures – Auditor qualification

Auditor qualification activities will be assessed and evaluated using remote techniques (e.g. through tele-/videoconferencing, web meetings, etc.), the precise nature of which will be discussed during planning. Auditors qualified using remote techniques will then be able to complete certification audits in their own country and qualify in-country auditors, provided all other CCS requirements have been met.

Once the travel situation improves, in-person activities will resume.

Audit support

WHO-supported initial audits – Package 3

Package 3 countries are those hosting only one PEF. These countries will be provided with a WHO-appointed audit team to support the NACs in completing the initial certification audit of their PEFs, but with responsibility for the arrangement of subsequent periodic and recertification audits resting with the NACs. Package 3 countries will therefore need to develop a programme to manage certification activities post-TS. This will be discussed during the CEV.

COVID-19 interim measures – Containment certification

PEF certification audits will be performed using remote auditing techniques (e.g. through tele-/videoconferencing, web meetings, etc.), the precise nature of which will be discussed during planning. Certificates issued where remote auditing is adopted will state the conditions under which these certificates were granted (remote audit) and will be accepted by the GCC, provided all other CCS requirements have been met.

Once the travel situation improves, in-person activities will resume.

TECHNICAL SUPPORT PREREQUISITES AND IMPLEMENTATION

The AQAS plan seeks to address current challenges and provide PEF-hosting countries with the opportunity to successfully complete containment certification activities based upon their situation and role in the eradication programme. However, key to success is a transparent and detailed agreement between all parties regarding roles and responsibilities, schedules, the availability of auditors (WHO and NACs) and access to suitably prepared facilities in order to conduct qualification and certification activities. Several prerequisites must therefore be addressed prior to any TS package being agreed:

1. NAC readiness:
 - a. Establishment of functional and suitably resourced NACs, including the availability of candidate auditors (if required), the development of NAC containment certification schemes, PEF engagement mechanisms, etc.;
 - b. Evidence that PEFs are prepared to participate in certification activity and are suitably engaged and ready, including gap assessment reports, etc.;
 - c. Commitment to meeting agreed timelines associated with the AQAS plan and related TS;
 - d. Provision of suitable candidate auditors with associated qualification, competence management and continuity mechanisms for in-country certification, and/or alternative arrangements if in-country capability will not be achieved/maintained;
 - e. Agreement that the WHO team will have full access to all relevant documents, personnel and facilities as per the NAC throughout TS-related activity;
 - f. Acceptance of the need for and adherence to agreements addressing NACs' resource commitments that fall outside the TS provided by WHO; and
 - g. Agreement to provide support with visas, services and other necessary country-specific arrangements.
2. WHO readiness:
 - a. Consultations with individual NACs and associated engagement and management of the overall TS package and process with associated country liaison;
 - b. Development of the TS delivery model and associated mechanisms; and
 - c. Early completion of required planning and preparatory activities critical to the success of the TS programme.

CONCLUSIONS

An AQAS plan has been developed that can support the aim of certifying all PEFs within the time frame addressed by the current Polio Endgame Strategy 2019–2023. The plan also supports the development of auditing capability at the global level to ensure the establishment of a sustainable mechanism for the ongoing certification of PEFs around the world. Four packages with differing levels of support have been defined, allowing some countries to develop in-country auditing capacity and others to rely on external provision following completion of the TS programme. An additional area highlighted relates to travel restrictions that are likely to persist for a prolonged period of time due to COVID-19 and the associated provision for remote TS delivery mechanisms during this period.

The GCC and GPEI look forward to working with NACs and PEFs to implement the AQAS plan and achieve containment certification for all PEFs.

ANNEX 1: KEY BENEFITS AND RISKS

The AQAS plan builds upon the strong basis already in place from previous activities that have led to almost all NACs being formally established and many PEFs receiving CPs. In addition, a large pool of candidate auditors has been trained, along with wider training and outreach activities provided across all WHO regions with widespread buy-in to GAPIII and the CCS.

Although details have to be added to the plan in terms of implementation, the approach presented is considered feasible and realistic, provided the assumptions described in the AQAS are met. The proposed timeline from 2021 to 2023 also allows the implementation of activities with a degree of flexibility while encouraging NACs and PEFs to conform to GAPIII and CCS requirements.

Key benefits include:

1. a realistic aim to certify all PEFs by the end of 2023 to coincide with the current eradication strategy end date;
2. a flexible approach enabling resources to be allocated where needed;
3. direct engagement with NACs and the establishment of plans for auditor qualification and PEF certification to defined timelines;
4. an ability to provide an appropriate level of in-country TS to adequately facilitate the certification process; and
5. a clear plan that can be measured and monitored by the GCC as countries move towards full GAPIII compliance.

However, several challenges related to key risks remain, described in Table A1.1 with associated mitigating measures.

Table A1.1. Risks and mitigating measures

Risk	Mitigating measures
Unestablished NACs, such that in-country certification cannot proceed	<p>Clarity on the implications of failing to certify PEFs to defined timescales</p> <p>Publication of progress reports relating to GAPIII and certification</p> <p>Continuing country engagement and advocacy through WHO and the GCC</p>
Challenges with NACs' in-country auditor capacity (e.g. high turnover, unavailability of personnel)	<p>NACs will be required to describe how this situation will be addressed as part of the agreement with WHO prior to the provision of an appropriate TS package</p> <p>NACs with two or more PEFs will be expected to maintain the ability to recruit, train and qualify their own audit teams as part of sustainability planning</p> <p>NAC certification management systems will be discussed during CEV and qualification activities</p> <p>Auditors may be available to NACs from external sources as global capacity increases</p>

Risk	Mitigating measures
Lack of progress with AQAS and the NACs' certification of PEFs	<p>Clarity on the implications of failing to certify PEFs to defined timescales</p> <p>Publication of progress reports relating to GAPIII and certification</p>
Timelines and additional commitments not respected by all parties	<p>Clarity on the implications of failing to certify PEFs to defined timescales</p> <p>Publication of progress reports relating to GAPIII and certification</p>
Inability to travel due to COVID-19 situation	<p>Most activities planned from 2021 onwards when travel and access to countries may be less problematic</p> <p>Ability to conduct some activities remotely (at least in part) should it be necessary to do so</p> <p>Plans for remote activities as set out in this document</p>
NACs' unwillingness to allow audit activity to proceed (e.g. non-acceptance of external auditors/auditor assessors/remote audits, lack of willingness to share information online or with the WHO team)	<p>Clarity on the implications of failing to certify PEFs to defined timescales</p> <p>Publication of progress reports relating to GAPIII and certification</p>
PEFs unwillingness to allow audit/auditor qualification activity to proceed (e.g. non-acceptance of external auditors/auditor assessors/remote audits, lack of willingness to share information online or with the WHO team)	<p>Clarity on the implications of failing to certify PEFs to defined timescales</p> <p>Publication of progress reports relating to GAPIII and certification</p>

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