

Report of CAG ad hoc TC (CAG TC4) on Tertiary Safeguards of Facility Location
and Associated Environmental Controls Described in GAPIII

14 August 2018

List of Abbreviations:

CAG	Containment Advisory Group
CCS	Containment Certification Scheme
CP	Certificate of Participation
CWG	Containment Working Group
EDS	Effluent decontamination system
GAPI	WHO Global Action Plan for laboratory containment of wild polioviruses (1st ed, 1999)
GAPII	WHO Global Action Plan for laboratory containment of wild polioviruses (2nd ed, 2004)
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use or Global Action Plan for Poliovirus Containment (3rd ed, 2014)
GCC	Global Certification Commission for the Eradication of Poliomyelitis
IPV	Inactivated Poliovirus Vaccine
NAC	National Authority for Containment
PEF	Poliovirus-essential facility
PV	Poliovirus
R ₀	Basic reproductive rate
SAGE	Strategic Advisory Group of Experts on Immunization
TC	Teleconference
WHO	World Health Organization
WSH	Water, Sanitation and Health
WPV	Wild Poliovirus

Participants:

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Background

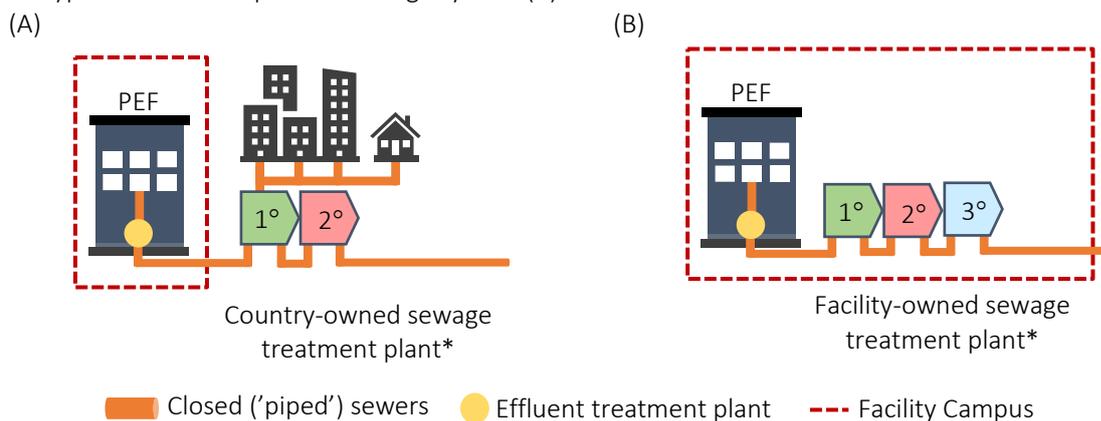
CAG has been requested to provide guidance to the Containment Working Group (CWG)¹ of the Global Certification Commission for the Eradication of Poliomyelitis (GCC) on alternative measure of compliance proposed by a designated poliovirus-essential facility (PEF) to the National Authority for Containment (NAC) as meeting the intent of the tertiary safeguard requirement described in GAPIII and GAPIII-Containment Certification Scheme (CCS) (Table 1).

¹ Terms of Reference of CAG and CWG. Available at: <http://polioeradication.org/who-we-are/governance-and-structure/>

Table 1: Tertiary safeguard of facility location and environmental controls described in GAPIII or GAPIII-CCS (left) and the proposed alternative measures of compliance (right)

<p>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.</p>	<ul style="list-style-type: none"> • Area surrounding the facility has no government entity-owned sewage system. The government has no plans to do so soon • Facility has its own ‘open’ sewage system with tertiary effluent treatment performed on campus • Inactivated effluents from its PEF will be conveyed in a ‘closed’ piped sewage system to its effluent treatment plant, undergo up to tertiary effluent treatment on campus before being discharged (Figure 1) • If compliant, the responsibility for implementation of tertiary safeguards of facility location will be transferred from the country to the facility
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Figure 1: GAPIII tertiary safeguards of facility location requires the siting of facilities in areas with low transmission potential (R_0) for WPV i.e., in areas with closed sewage systems with a minimum of secondary treatment of effluents (A) and alternative measure of compliance with this requirement based on type and ownership of the sewage system (B)



* Sewage treatment levels: 1° (physical - settlement of suspended solids); 2° (biological - aerobic e.g., aeration tanks or anaerobic) and 3° (advanced – various types exist depending on requirements for receiving water e.g., UV, filter membranes) treatment levels. All treatment levels may include some part of the treatment process occurring in areas exposed to air e.g., aerated grit chamber, aeration tanks, aerators, etc.

In addition, there is a need for CAG to consider if the present definition in GAPIII or GAPIII-CCS are sufficient and clear or if further discussions are needed to provide clarity on this issue.

The intent of tertiary safeguards in GAPIII in particular ‘closed sewage system’

Safeguards, specifically those related to sewage systems, were first introduced in the WHO global action plan for laboratory containment of wild polioviruses (GAPI, 1999) and later in GAPII (2004), with the simple intent of avoiding the direct discharge of effluent from a facility into the environment. The term ‘closed system’ was used to differentiate between systems in which effluent were treated on-site prior to release and those in which untreated effluent were discharged into the environment. Recognition of the requirement to provide on-site treatment of effluents prior to its release continued through to GAPIII

(2014) and extended to include some form of back-up should the primary effluent inactivation procedure or equipment [e.g., effluent decontamination system (EDS)] of the PEF fail.

The intent in GAPIII was to require primary inactivation of effluents on-site (as part of facility-based primary safeguards), followed by the transfer of inactivated effluents through some form of ‘closed’ or ‘piped’ system to a government entity-owned public or community sewage treatment plant.

There has been little attempt to engage water, sanitation and hygiene (WSH) or public health engineers to provide clear definitions of the terms used in GAPIII, which has resulted in some ambiguity in the terminology used.

Discussion

The intent of tertiary safeguards in the context of GAPIII is to protect the local community in the event of failure of primary safeguards (e.g., effluent inactivation procedure or equipment failure), contaminated effluent from the facility would not go out into the local environment untreated but would be subjected to sewage treatment steps prior to release into the environment (Table 2).

There has however, been little discussion on the following related issues:

- Management of the mixing of inactivated facility effluent with community wastewater and stormwater
- Technical specifications of standard sewage treatment processes or steps
- Proximity of the sewage treatment plant to the facility
- Ownership of the sewage system and treatment plant and responsibility to implement and maintain this requirement.

Table 2: The biorisk management in designated PEFs is achieved through the implementation of primary, secondary and tertiary safeguards in GAPIII, as applicable to the type of poliovirus materials held

Primary safeguards of facility containment	
Minimizes the likelihood of a facility-associated poliovirus release	Prevent infection of operator or release of contaminated materials by strict adherence to GAPIII
Secondary safeguards of population immunity	
Minimize the consequence of a facility-associated poliovirus release into the community	IPV doses and IPV coverage ²
Tertiary safeguards of facility location and associated environmental control	
Minimizes the risk of re-establishing WPV circulation in the event of re-introduction	Siting of facilities in areas with closed sewage systems with secondary or greater effluent treatment in areas with low transmission potential (R_0) for WPV. Environmental controls include sanitation and hygiene conditions (good personal, domestic and environmental hygiene standards).

The design of most government-entity owned public sewage plants generally include the following treatment steps: primary (i.e., ‘physical’ separation or sedimentation), secondary (i.e., biological process e.g., aeration) and tertiary (i.e., chemical or UV) treatment steps. The secondary treatment step involves aerobic bacterial degradation of material in vats that are ‘open’ to the atmosphere. The tertiary treatment

² Current recommendations by SAGE on secondary safeguards for countries hosting PEFs: Available at: [Meeting of the Strategic Advisory Group of Experts on immunization, April 2018 – conclusions and recommendations. Weekly Epidemiological Record 2018; 93:329–44](#)

includes chemical inactivation of bacteria and viruses. Primary, secondary and tertiary safeguards are required for PEFs that handle and store WPV materials after WPV eradication (i.e., Phase III of GAPIII).

Countries designating PEFs are expected to understand the responsibilities inherent in complying with crucial primary, secondary and tertiary safeguards and to ensure oversight and verification processes are in place. GAPIII and the CCS do not necessarily make clear the intent of tertiary safeguards, as described above, and may require some revision to provide greater clarity in its definition, purposes and intent.

CAG deals with generic issues concerning containment implementation, and where a submission is made that has not already been provided a generic response, CAG is expected to provide a response that in the future will be used by NACs in their specific circumstances. The CAG is looking into ways of improved collaboration together with the CWG to provide guidance on alternative measures of compliance on a needs basis.

Conclusions and Recommendations

The acceptability of the alternative measures of compliance proposed by the designated PEF will be raised for discussion again at the Third Meeting on 13-14 December 2018. In the interim:

1. As a comprehensive risk management approach, the designated facility should be encouraged to carry out a risk assessment of its entire sewage treatment plant. Risk assessments should not be limited only to the primary effluent inactivation step.
2. In line with the 2018 World Health Assembly Resolution WHA 71.16³ adopted by all Member States, such facilities and those alike must be formally engaged in the CCS by submitting to their NAC their applications for certificate of participation no later than 31 December 2019.
3. The secretariat is requested to prepare the appropriate background documentation on the proposed definition of tertiary safeguards as is currently described in GAPIII for deliberation of the CAG at its Third Meeting on 13-14 December 2018.

Submission of technical issues linked to GAPIII or containment of polioviruses for the consideration of the CAG, should be made using the [CAG submission form](#), and should be emailed to containment@who.int. The deadline for submission of issues for consideration of the CAG at its Third Meeting is 23 November 2018. Submissions received after the deadline will be addressed through a teleconference.

³ Seventy-First World Health Assembly (2018) Resolution WHA71.16 Poliomyelitis – containment of polioviruses. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf