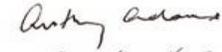


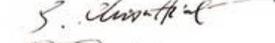
Declaration

We, the members of the Global Commission for the Certification of Poliomyelitis Eradication, conclude today, 20th September 2015, that indigenous wild poliovirus type 2 has been eradicated worldwide.

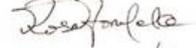
Anthony Adams, Chair



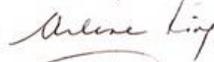
Supamit Chunsuttiwat



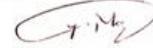
Rose Gana F. Leke



Arlene King



Yagob Al Mázrou



David M. Salisbury



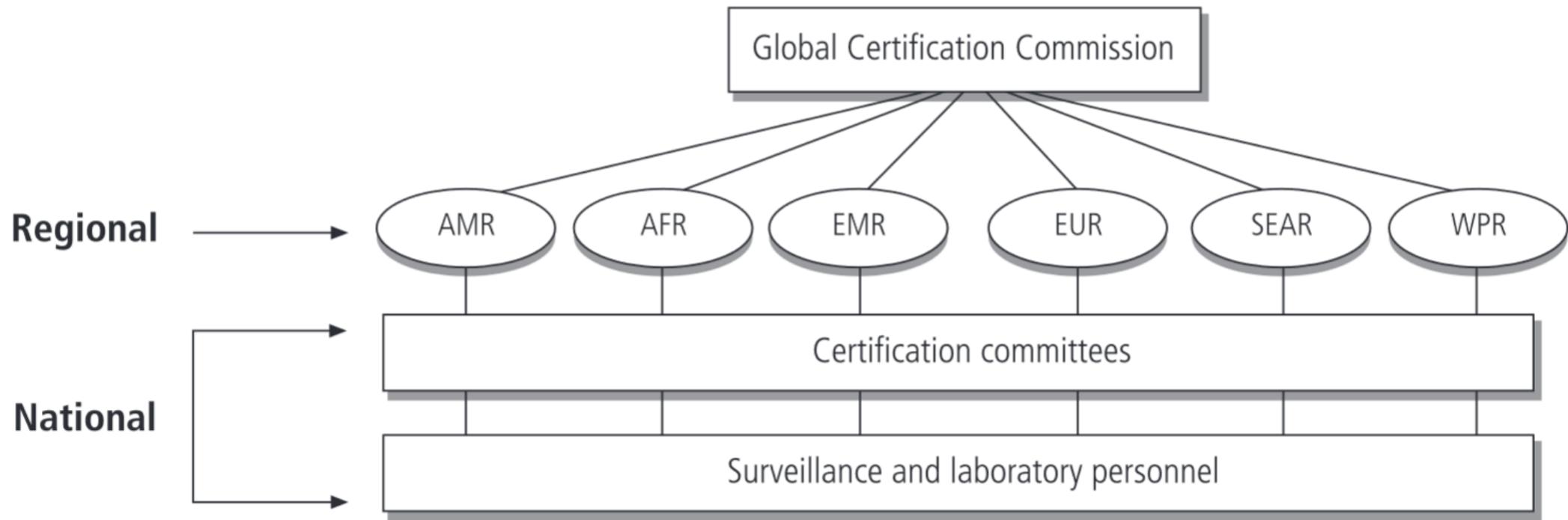
Bali, Indonesia



The Global Commission for the Certification of Polio Eradication (GCCPE)

In 1995, the Director-General of WHO charged the GCC with three tasks:

1. defining the parameters and processes by which polio eradication will be certified, guiding regions and countries in establishing their data collection processes;
2. receiving and reviewing the final reports of RCCs of polio eradication;
3. issuing, if and when appropriate, a final report to the Director-General of WHO certifying that global polio eradication had been achieved.



AFR = African Region

AMR = Region of the Americas

EMR = Eastern Mediterranean Region

EUR = European Region

SEAR = South-East Asia Region

WPR = Western Pacific Region

WHO 03.220

Hierarchy of Certification of Eradication

The main criteria set by the GCC (in 2004) as prerequisites for global polio-free certification were to show:

1. The absence of wild poliovirus, isolated from cases of acute flaccid paralysis (AFP) (suspect polio), healthy individuals, or environmental samples, in all WHO regions for a period of at least three years in the presence of high- quality, certification-standard surveillance;

2. The containment of all wild poliovirus stocks in laboratories through completion of the requirements of the WHO global action plan for laboratory containment of wild polioviruses

- ❑ During its first meeting, the GCC defined global polio eradication as “the eradication of all wild polioviruses”, and specified that “the occurrence of clinical cases of poliomyelitis caused by other enteroviruses, including attenuated polio vaccine viruses, does not invalidate the achievement of wild poliovirus eradication”.
- ❑ The GCC recognized, however, that the full benefits of polio eradication would only be realized in the absence of cVDPV, and requested WHO to develop a separate process for verifying the absence of cVDPV in the post-certification era, after cessation of oral poliovirus vaccine use.

Final National Certification reports and Annual Updates*

- ❑ Country background information (demography, population distribution, high-risk groups, migration patterns, health care systems, etc.);
- ❑ Structure and responsibilities of national units concerned with polio eradication;
- ❑ History of confirmed polio cases and polio-compatible cases;
- ❑ Surveillance activities, including AFP surveillance quality*;
- ❑ Information about the polio laboratories serving the country, including documentation of the results of WHO accreditation*;
- ❑ Progress towards laboratory containment*;
- ❑ Plan of action for handling wild poliovirus importations, including their detection, investigation, and intended response procedures*;
- ❑ Routine and supplementary immunization activities*.

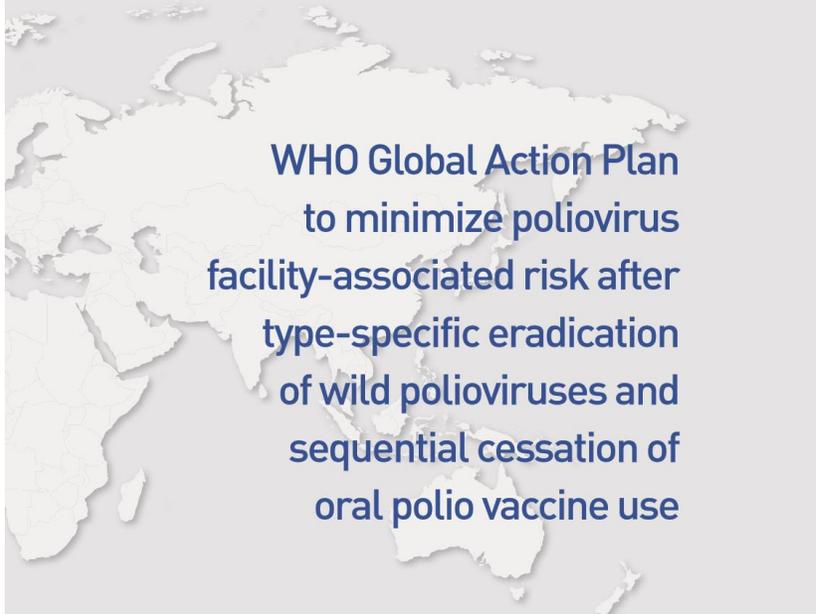
Surveillance methods used by countries, as reported to RCCs

- ❑ AFP surveillance has been established as the Gold Standard.
- ❑ RCCs and GCC can assess the quality of surveillance: AFP rate, sample collection and sample quality.
- ❑ AFP surveillance has failed in industrialised countries – either abandoned or continued at substandard indicators' levels.
- ❑ In industrialised countries AFP surveillance has been replaced or augmented with enterovirus surveillance and/or environmental surveillance.
- ❑ There are no criteria that link enterovirus surveillance or environmental surveillance with AFP surveillance performance.
- ❑ Apart from Israel, where AFP failed (because there was no paralysed person), there has not been a polio outbreak in any other Enterovirus or Environmental surveillance country to know if it would have been detected through either method.

Recommendations from July 2017 GCC meeting.

- ❑ NCCs should change the content of their Annual Update reports to include a risk assessment relevant to their country circumstances. This practice needs to be implemented promptly.
- ❑ RCCs and GCC should work with their respective Secretariats to adopt and utilize a more comprehensive approach to assess risks and the impact of risk mitigation activities.
- ❑ WHO Regions should update their polio risk assessment methodologies, including considering new risks (e.g. iVDPVs, breaches of containment).
- ❑ In order to allow the GCC to compare risks across countries and WHO Regions, the approach to risk assessment should be harmonized across Regions, and implemented in an electronic data collection tool that will facilitate review of the evidence by the GCC.
- ❑ The GCC secretariat should work on and submit a new harmonized approach to risk assessment to GCC for review at its next meeting.

<http://polioeradication.org/wp-content/uploads/2017/09/GCC-16th-meeting-report-0405072017.pdf>



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



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

GAPIII-CCS

GAPIII objective

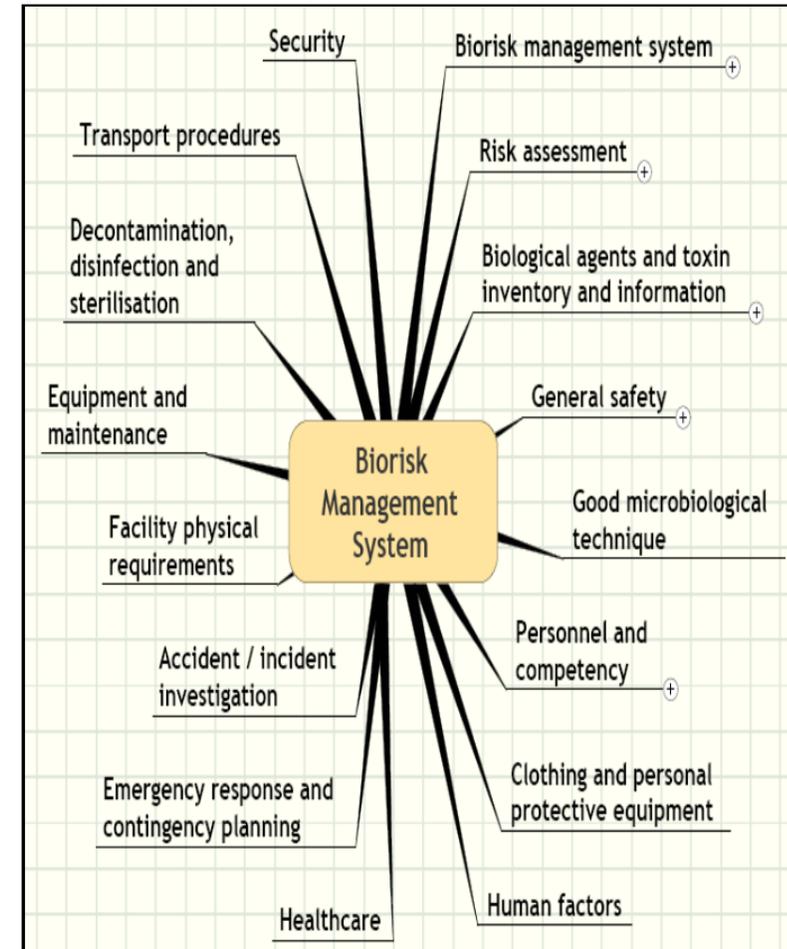
Only those facilities that serve critical functions would be expected to continue to operate, thereby reducing the number of Poliovirus-Essential Facilities (PEFs) worldwide and minimizing the risk of release of poliovirus post eradication to as close as possible to zero.

Why does GAPIII adopt a biorisk management philosophy and approach?

- Post-eradication, the consequences of a reintroduction of poliovirus into what could be increasingly vulnerable populations could be devastating
- Laboratories and vaccine production facilities will constitute the remaining sources of virus (in addition to shedders)
- Risk tolerance in terms of the potential for a breach of containment is extremely low
- The objective of developing the biocontainment standards in GAPIII was to provide a very high level of assurance that there would be no releases of virus post-eradication
- The biorisk management approach as defined in CWA 15793 was recognized as providing the highest level of assurance available

GAPIII annexes

- **Annex 2**
 - For certification of PEFs holding WPV/NDPV
- **Annex 3**
 - For certification of PEFs holding only OPV/Sabin
- **Annex 2 vs Annex 3:**
 - Identical except for certain facility containment-specific areas applying in Phase III for containment of all wild poliovirus
- **Annex 6**
 - Surveillance laboratories



What are Annexes 2 and 3 designed to do?

- Define the scope for a biorisk management system
- Facilitate the identification of current best practice in the field
- Risk-based approach
- Allow for a variety of solutions when managing biorisk within an organization
- Drive continuous improvement
- Identify and control poliovirus-specific risks and controls with a biorisk management framework
- Enable facilities to assure stakeholders of responsible and proportionate biorisk management, including providing a basis for establishment and implementation of adequate national and international oversight mechanisms

Nature & type of facilities addressed by CCS

- Poliovirus vaccine production facilities, including associated QC laboratories, animal houses, filling lines, packaging areas, vaccine/seed storage areas and other relevant functions
- QC laboratories of NRAs, involved in the control and release of poliomyelitis vaccines
- Facilities that conduct basic and biomedical applications/research/clinical trials with poliovirus
- Facilities using polio material for quality control, testing and/or validation purposes, and those producing diagnostic kits and/or materials for reference or other form of testing
- Repositories, culture collections and other specialized and dedicated forms of storage
- Sites used to dispose of and/or destroy stocks (e.g. incinerators, landfill)
- Collections of stool or other materials where the presence of poliovirus may be reasonably expected

National Authority for Containment (NAC)

- Ensures and demonstrates that the required primary, secondary and tertiary safeguards are met
- Establishes national containment certification mechanisms aligned with the CCS
- Reviews and processes CCS applications in consultation with the GCC, ensuring only relevant facilities enter the CCS process
- Ensures PEFs are appropriately assessed and comply with GAPIII requirements
- Ensures effective CCS certification programme and procedures are established and maintained
- Provides relevant parties (PEFs, audit team members, GCC) with appropriate access to pertinent information required for containment certification activities
- Adheres to principles and practices set out in ISO/IEC 17021-1:2015 – Requirements for bodies providing audit and certification of management systems
- Issues, suspends or revokes certificates of containment, in consultation with GCC
- Determines the cost of GAPIII certification activity and how the cost will be met

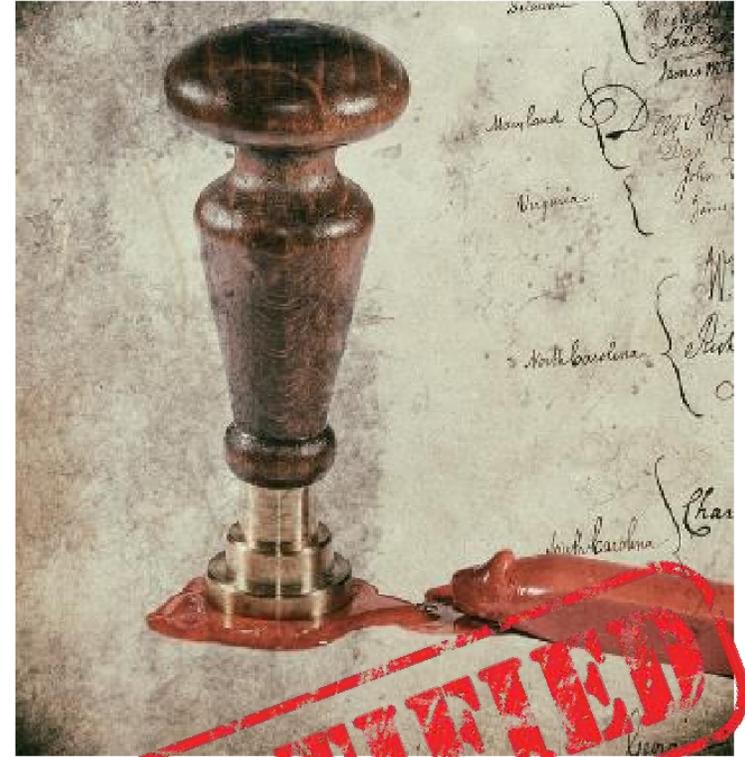
Types of CCS certificates

- **Certificate of Containment (CC)**
 - To be achieved and maintained by PEF in post eradication era under GAP III
- **Interim Certificate of Containment (ICC)**
 - For facilities not meeting all requirements, but requiring short term approval while more permanent conditions are finalized for CC or cessation of work
- **Certificate of Participation (CP)**
 - For facilities engaging in the CCS certification process who may not yet be meeting all requirements and may yet to have been formally assessed against GAP III requirements or cessation of work

Only facilities holding a valid CP/ICC/CC are allowed to pursue work and storage of poliovirus

Poliovirus-Essential Facility (PEF)

- Establishes, implements & maintains GAP III biorisk management system
- Provides relevant parties (NAC, audit team members, GCC) with access to all information and facilities relevant to containment certification activities
- Achieves & maintains containment certification
- Reports to NAC and relevant parties any event, change or issue that could jeopardize the status of their containment certification



Pre-requisite for PEF qualification

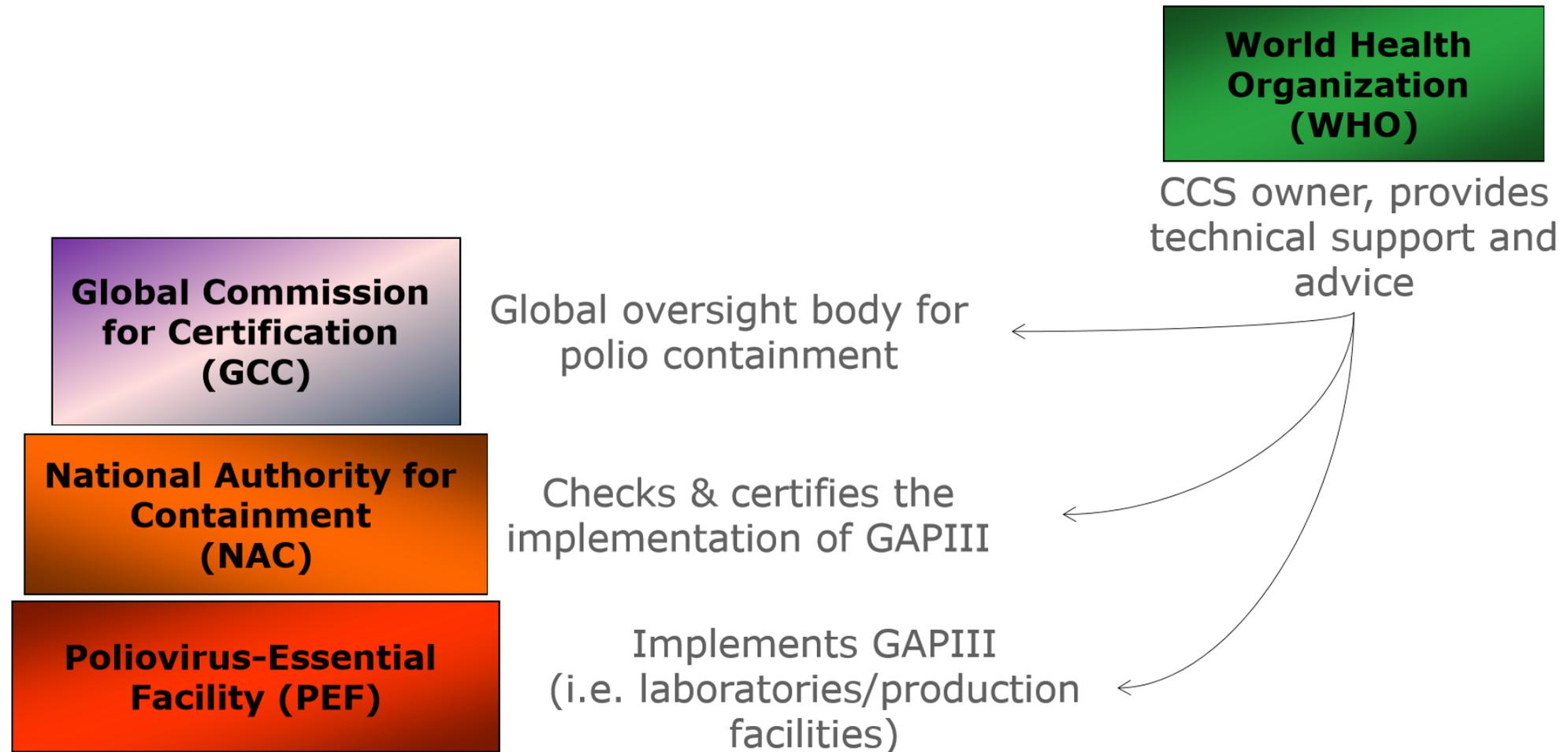
- A facility can only be awarded a certificate (CP/ICC/CC) if the hosting country has shown that the secondary and tertiary safeguards have been met and the NAC is set up
- Secondary safeguards - population immunity

2° safeguards: Population immunity in country hosting the facility	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
IPV doses	≥ 1	≥ 1	≥ 3
IPV coverage	= DTP3 coverage	= DTP3 coverage	>90%

- Tertiary safeguards - environment & location

3° safeguards: Environment & location	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
Siting of facilities in areas with low transmission potential (R_0) for wild polioviruses	No	No	Yes

GAPIII CCS hierarchy



GCC and GCC-CWG

GCC's new containment role:

- Reviews applications to ensure that a designated PEF is eligible to join the CCS process
- Approves/endorsees the process to award containment certificates
- Reviews and approves NAC's assessments of PEFs' containment activities
- Approves/endorsees the issuance of containment certificates (CP/ICC/CC)
- Acts as a global oversight body and confirms the global containment of polioviruses

GCC-CWG on behalf of GCC



World Health Organization (WHO)

- Develops, maintains and revises CCS
- Provides secretariat services in support of GCC
- Provides coordination, implementation support, technical assistance and expert advice regarding CCS process to countries, NACs and the GCC (not to PEFs)
- Addresses feedback relating to CCS



Recent experiences

- Shortage of IPV supply
- Use of mOPV2 for outbreak response
- Certification scheme moving slowly
 - 18/28 NACs appointed
 - No known CP applications
 - No known audits
- 95 designated PEFs to date
 - Original target 20
 - Number approximately doubled since January 2016

Recent experiences

- **Some resistance to proposed controls**
 - Manufacturers (e.g. showering)
 - NACs (e.g. preference for existing national controls)
- **Significant incidents**
 - GSK (WPV3, 2014)
 - BBio (WPV2, 2017)
- **First CAG meeting**
 - Little change in GAPIII controls
 - Requests for evidence if changes are to be made

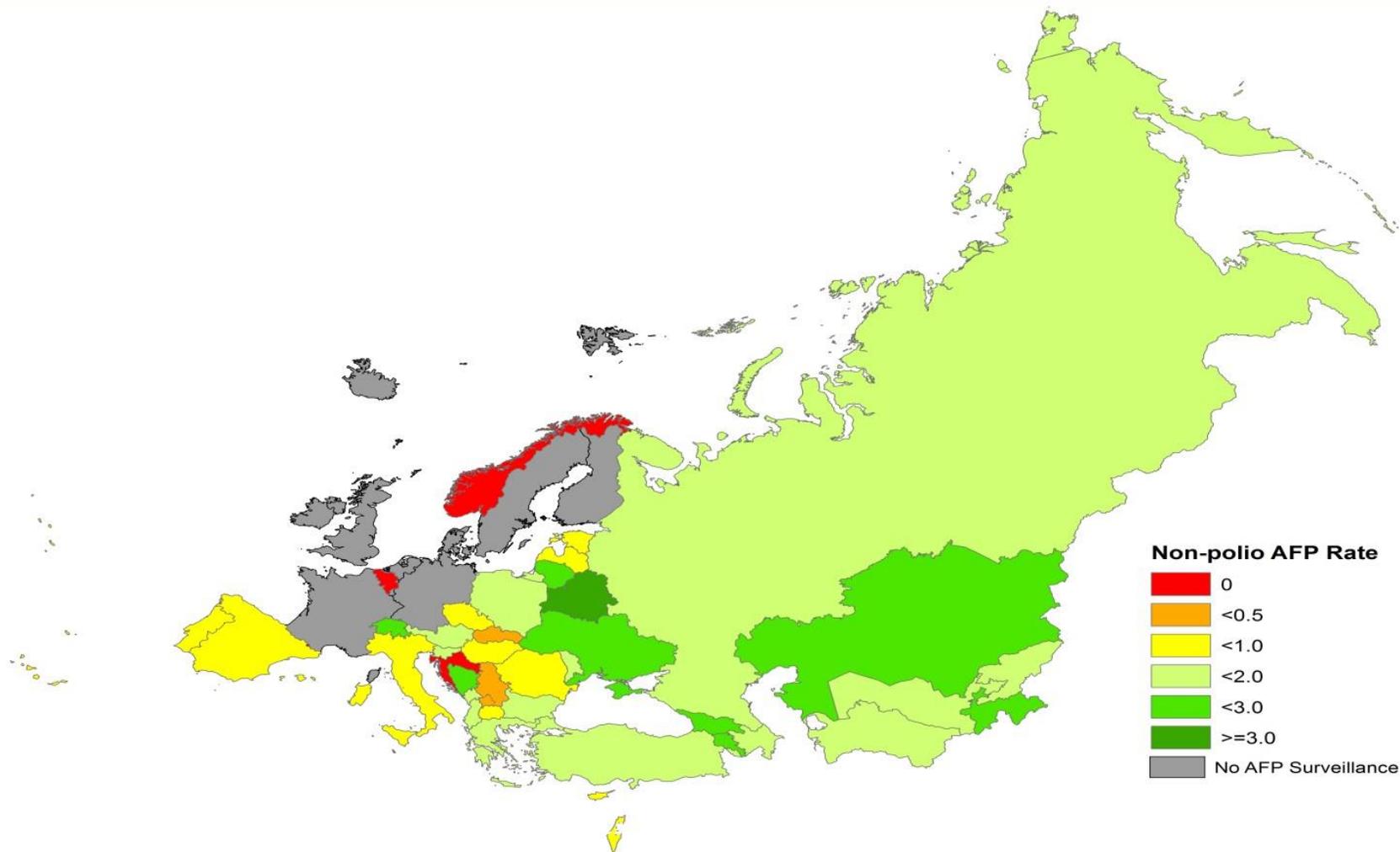
WHO Europe Poliomyelitis Eradication Transmission Interruption Certified in 2001.



European Region: Polio surveillance by type



Non-polio AFP Rate, WHO European Region, 2016



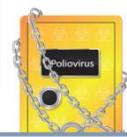
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
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Source: CISID AFP Database

Data as of: 02 May 2017

Map Production: Vaccine-preventable Diseases and Immunization (VPI),
Division of Health Emergencies and Communicable Diseases,
World Health Organization Regional Office for Europe.

WHO/Europe progress on PV Containment procedures



Status by the date: 27.09.2017		Number	Member States
No WPV2/No Sab2		38 (of them: no PVs = 15; no WPV/no Sab2 = 18; no WPV2/no Sab2 = 6)	AND, ARM, AZE, BIH, CYP, ICE, KGZ, LUX, MLT, MNE, MON, SMR, TJK, MCD, TKM; ALB, BUL, CZE, EST, FIN, GEO, GRE, IRE, KAZ, LVA, MDA, POL, PRT, SVK, SVN, UKR, UZB; AUT, DEU, ISR, NOR, SWI, TUR
No WPV/have Sab2	Plan to destroy Sab2	2	LTU, SPA
	PEF-Sab2	1	CRO
WPV2/Sab2	PEF-WPV2/Sab2 COUNTRY(Number of PEFs, if >1)	12 (of them: PV2 only in PEF = 10; PV2 not only in PEF = 2)	BEL(6), BLR, DNK(2), HUN, NET (7-9), ROM, RUS(7), SRB, SWE, UNK(3); FRA(4+2?), ITA(3)
MS with PEFs (total = 13)	NAC +	8	BEL, BLR, CRO, FRA, HUN, RUS, SWE, UNK
	Acting NAC	2	DNK, ITA
	No NAC yet	3	<u>NET</u> , ROM, SRB

NET – there is a contact person to communicate on NAC issues

Europe: PV Containment – Summary

Poliovirus containment is a complex program with various challenges at the global, regional and national levels

Regional highlights:

- Phase I has been completed but the search for stocks of “containable” PV will continue in the foreseeable future
- The majority of countries with PV2 are located in the European Union (EU) countries
- The highest number of prospective PEFs are located in the EU as well
- Countries are now in the process of preparing for PEF(s) certification
- External private investors are looking at European biopharma industry to setup polio vaccine manufacturing in the Region – number of PEFs is expected to grow
- Lack of live virus-independent methods for immunity testing further contributes to high number of PEFs

EURO Risk Assessment

- **Three groups of indicators (components):**
 - **Population immunity indicators**
 - **Surveillance indicators**
 - **Other factors (outbreak preparedness and response)**
- **Categorize as high, intermediate, low risk**
 - **Numeric assessment and expert (RCC) inputs.**

EURO Risk Assessment Method

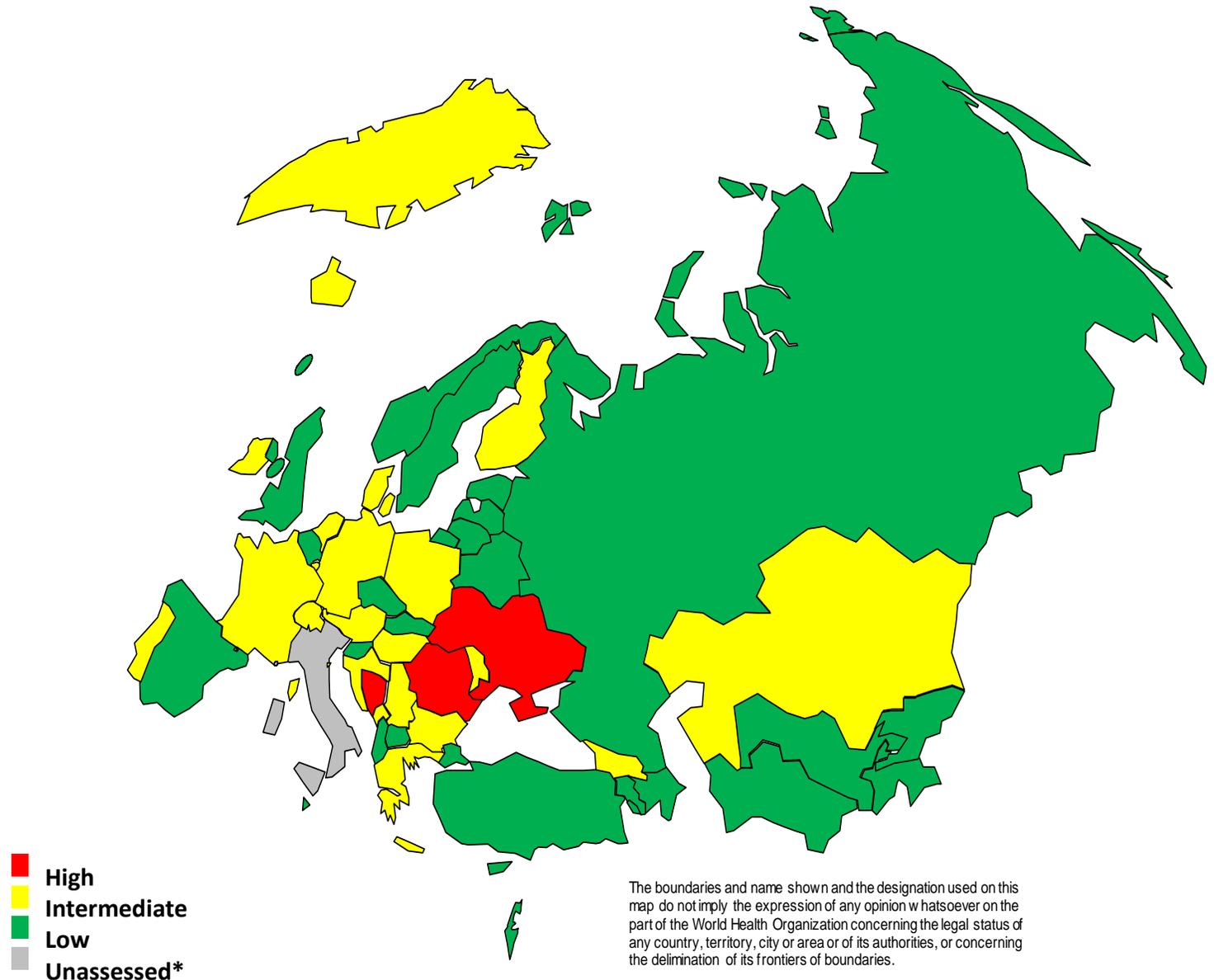
- Relatively simple algorithm
- Scoring reflects weight given to population immunity compared to surveillance
- Surveillance scoring challenging
 - Some countries without AFP surveillance
 - Lack of standardization for supplementary surveillance (ENV, EV)
- Meaningful process to assess risk
 - Review of critical programme components
 - Summary and comparison across Member States

Poliovirus Surveillance

Country	2014 AFP index	2015 AFP index	2016 AFP index	Timeliness (%) of reporting to WHO	Timeliness (%) of samples processing	Supplementary surveillance
Country A	No AFP surveillance					EV-
Country B	0.47	0.47	0.0	92%	N/A	EV+,ENV+
Country C	No AFP surveillance					EV-; ENV+
Country D	No AFP surveillance					No data
Country E	0.68	0.68	0.68	93%	100%	EV+,ENV-
Country F	1.0	0.8	1.0	66%	100%	EV+
Country G	0.47	0.11	0.2	55%	90%	EV+
Country H	No AFP surveillance					EV+

WHO EUR Risk Assessment – June 2017

- The EU-RCC met from 30 May – 1 June 2017 to review the 2016 reports from the Region.
- Risk is assessed based on surveillance, population immunity and outbreak preparedness
- High-risk: Bosnia-Herzegovina, Romania, Ukraine.
- Unassessed: Italy



Risk Assessment Methods – 2017

- New process to look at risk and subcategorize
 - Risk subcategories
 - WPV importation
 - VDPV emergence
 - Containment breach
 - Response and preparedness capacity
 - Vulnerable, underserved populations
- ASR – 2017 identify risk and mitigation activities

GCC linkage to post-certification strategy (PCS)

GCC conclusion

- The GCC notes that parameters for global certification established by the GCC will become key drivers to influence strategies and standards proposed by the PCS.
- Thus, the scope and type of activities in preparation for global certification (e.g. management of PV-positive environmental samples, positive contacts, VDPVs) will impact the:
 - PCS ‘protection strategies’,
 - readiness criteria for bOPV cessation,
 - outbreak response parameters, and
 - continuation and duration of key surveillance strategies.

Recommendation 27

The GCC recommends that the development and evolution of the PCS be closely coordinated with the GCC and reviewed before, at the time of, and after global certification.

Important topics to discuss at subsequent GCC meetings

1. All aspects of **GCC involvement in containment**, through conducting a GCC meeting fully dedicated to this topic. This may include a session between the Chairs of the GCC and CAG, the GCC/CWG, and vaccine producers / vaccine industry representatives.
2. The best way to keep the GCC updated on Regional Risk Assessments prior to global certification, including the review and reporting of **risk assessment status between levels** (from NCC to RCC and from RCC to GCC), particularly for countries and Regions certified many years ago; this review should include an assessment of the possibility of undetected PV transmission, of surveillance quality and immunity levels, and of the status of containment.
3. The **certification standards** for polio surveillance (AFP, ES, supplementary methods), including the possibility of establishing different standards (e.g. for conflict-affected countries, recently endemic and certified Regions).
4. The **review of existing TORs of RCCs in all Regions** in order harmonize the work of RCCs to allow focus on the same key TOR components (e.g. prioritizing risk assessment versus monitoring other components of the polio endgame).
5. Discuss the intersection timelines for certification and for containment.
6. Linkage to other polio groups and committees– eg, SAGE Polio WG (SAGE), Cessation Risk Task Team (CRTT), CAG.