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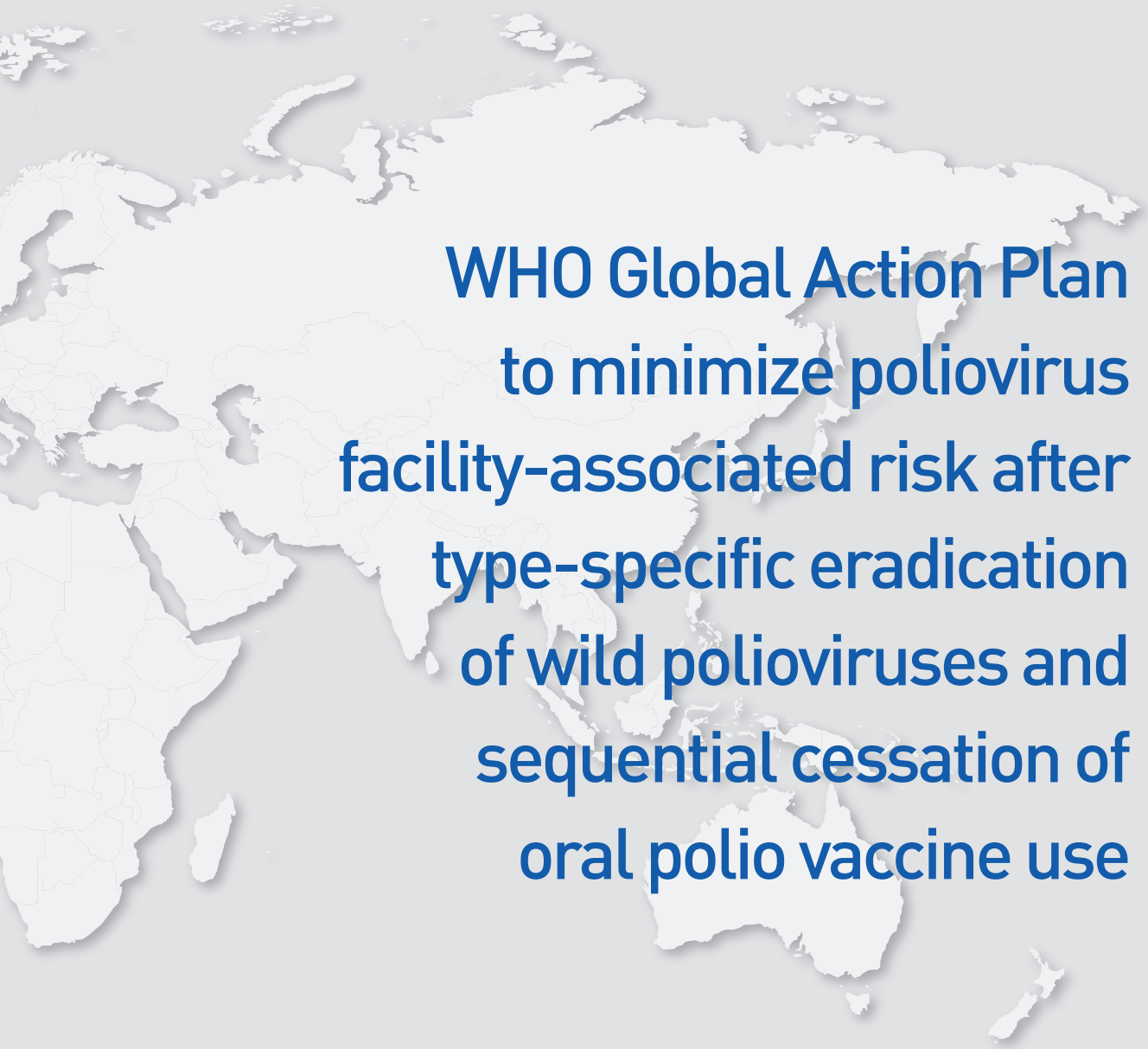

WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use

GAPIII

World Health Organization

WHO/POLIO/15.05

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After type-specific eradication and containment of wild poliovirus and cessation of oral polio vaccination, minimizing the risk of poliovirus reintroduction is critical. To prevent reintroduction, the number of international poliovirus facilities will need to be reduced to the minimum necessary to perform critical functions of vaccine production, diagnosis and research.

World Health Organization

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CONTENTS

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ABBREVIATIONS AND ACRONYMS

AFP	Acute flaccid paralysis
BSC	Biological safety cabinet
$CCID_{50}$	Cell culture infectious dose 50%
CEN	European Committee for Standardization
CWA	CEN Workshop Agreement
DTP	Diphtheria–tetanus–pertussis
DTP3	Diphtheria–tetanus–pertussis vaccine third dose
GAP	Global Action Plan
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
HEPA	High-efficiency particulate arresting
HSE	Health, safety, security and environment
IPV	Inactivated polio vaccine
Sabin-IPV	Sabin-inactivated polio vaccine
Salk-IPV	WPV-inactivated polio vaccine
µm	Micrometre
MoH	Ministry of Health
OPV	Oral polio vaccine
OPV2	Oral polio vaccine type 2
bOPV	Bivalent oral polio vaccine containing type 1 and type 3
mOPV	Monovalent oral polio vaccine containing one type only
mOPV2	Monovalent oral polio vaccine type 2
tOPV	Trivalent oral polio vaccine containing type 1, type 2 and type 3
PPE	Personal protective equipment
PV	Poliovirus
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
R_0	Basic reproduction rate
SOP	Standard operating procedure
VAPP	Vaccine-associated paralytic poliomyelitis
VDPV	Vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus type 2
aVDPV	Ambiguous vaccine-derived poliovirus
aVDPV2	Ambiguous vaccine-derived poliovirus type 2
cVDPV	Circulating vaccine-derived poliovirus
cVDPV2	Circulating vaccine-derived poliovirus type 2
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
iVDPV2	Immunodeficiency-associated vaccine-derived poliovirus type 2
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus type 1
WPV2	Wild poliovirus type 2
WPV3	Wild poliovirus type 3

INTRODUCTION

Launched in 1988, the Global Polio Eradication Initiative (GPEI) has been the largest international public health effort ever undertaken, involving billions of US dollars donated through GPEI partners, the dedicated efforts of governments at all levels, countless hours of volunteer services, and the immunization of billions of children with oral polio vaccine (OPV).

The *Polio Eradication & Endgame Strategic Plan 2013-2018* (the Endgame Strategy) (3) set the goal of a polio-free world by 2018. Achieving this goal requires: (i) completion of eradication to eliminate the risk of wild poliovirus (WPV) transmission; (ii) cessation of the use of OPV to eliminate the risks of vaccine-associated paralytic poliomyelitis (VAPP), chronic immunodeficiency-associated vaccine-derived poliovirus (iVDPV) and outbreaks of circulating vaccine-derived poliovirus (cVDPV) (4; 5); and (iii) implementation of poliovirus safe-handling and containment measures to minimize the risks of a facility-associated reintroduction of virus into the polio-free community.

The first step towards cessation of trivalent OPV (tOPV) use will be the withdrawal of OPV type 2 (OPV2), which has caused over 90% of cVDPV cases since the eradication of WPV2 in 1999. The resulting bivalent OPV (bOPV, types 1 and 3) will replace tOPV in global immunization programmes, facilitated by the introduction of at least one dose of inactivated poliovirus vaccine (IPV), composed of all three virus types.

Providing adequate IPV doses for all OPV-using countries will require both volume purchasing of existing IPV products and developing alternative low-cost IPV options (e.g. Sabin-IPV) for developing countries to meet programmatic needs.

Until cessation of OPV use, bOPV will be the vaccine of choice to respond to any WPV type 1 (WPV1) and WPV type 3 (WPV3) outbreaks, while monovalent OPV type 2 (mOPV2) will be the choice for responding to type 2 outbreaks. After OPV cessation, a combination of type-specific mOPV and IPV will be used to respond to any WPV or vaccine-derived poliovirus (VDPV) outbreak.

Global consensus to stop bOPV will require international assurance that the transmission of wild and vaccine-derived poliovirus has been interrupted; affordable, safe and effective IPVs are available; potential outbreaks from undetected or newly emerged cVDPV can be controlled; and the risk from facility-associated reintroduction of wild or OPV/Sabin polioviruses can be minimized.

This third edition of the Global Action Plan (GAPIII) aligns the safe handling and containment of poliovirus infectious and potentially infectious materials with the WHO Endgame Strategy and replaces both the 2009 draft version of the third edition posted on the GPEI website and the second edition of the *WHO Global Action Plan for laboratory containment of wild polioviruses* (6). The third edition:

- describes timelines and requirements to be:
  - completed in preparation for poliovirus type 2 containment
  - implemented throughout the poliovirus type 2 containment period
  - applied in the post-eradication and post-bOPV phase;

- addresses type-specific containment of WPV as well as OPV/Sabin polioviruses, consistent with the goal of sequential cessation of OPV use after type-specific WPV eradication (7);
- balances the need for equitable access to polioviruses, e.g. for vaccine production, throughout the poliovirus type 2 containment and post-eradication period, against the risk based on assessment findings, consequence models (8) and management strategies (Annexes 2 and 3);
- establishes the long-term goal of minimizing the risk of facility-associated poliomyelitis in the post-eradication/post-bOPV era by providing continued access to safe and affordable IPV or Sabin-IPV and by reducing to a minimum the number of facilities handling and storing polioviruses while serving critical functions and meeting all required safeguards.

GAPIII is an evolving document, subject to revisions as new information emerges relevant to achieving the appropriate balance between community risk and the systems and controls to manage that risk. The poliovirus "Biorisk management standard" (Annexes 2 and 3) provides the framework for facility certification based on the principles of a biorisk management system. This standard requires the institution/facility to understand the risks associated with its activities and to manage those risks in ways acceptable to the national and international bodies responsible for the oversight of work with polioviruses. National authorities are responsible for reviewing the application of these risk management standards and principles in local circumstances. Although Annexes 2 and 3 are written specifically for wild polioviruses and OPV/Sabin strains, respectively, as they exist at the present time, should novel strains emerge that are considered to be more attenuated, less pathogenic and safer than OPV/Sabin strains, the evidence will be reviewed by a panel of scientific experts convened by WHO to consider the controls applicable to their containment and safe handling.

RATIONALE

When WPV circulation is interrupted, interest in immunization against polio is expected to decline and population susceptibility will increase in many parts of the world. A reintroduction of WPV from a poliovirus facility risks the potentially serious consequences of re-establishing poliovirus transmission. When the use of OPV stops, many countries will continue high population coverage with IPV, other countries will have suboptimal IPV coverage, and still others may discontinue all national polio immunization activities. A reintroduction of an OPV/Sabin strain from a facility risks unrecognized virus transmission, reversion to cVDPV, and again the potential serious consequences of re-establishing poliovirus transmission (8).

Most countries will have no need to retain live polioviruses in the post-eradication and post-OPV era. Facility-associated risks in these countries can be eliminated by a thorough nationwide search for and destruction of all WPV and all OPV/Sabin infectious and potentially infectious materials.

Some countries will host a limited number of poliovirus facilities that serve critical international functions, including IPV and Sabin-IPV production, production and storage of mOPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, together with crucial research.

Each of these poliovirus-essential facilities should manage biorisk appropriately to minimize the risk of virus reintroduction into the community, with effective national certification and WHO verification programmes. The risk from a poliovirus reintroduction can be minimized by locating poliovirus-essential facilities in areas with high levels of population immunity, effective acute flaccid paralysis (AFP) and environmental surveillance, supplemented by efficient public health and response capacity. Consequences can be further minimized by working only with OPV/Sabin or alternative, more attenuated strains, which have lower basic reproduction rates (R_0) than WPV (8). Minimizing the number of poliovirus-essential facilities worldwide further reduces the magnitude of the risk, facilitates national and international oversight, and strengthens the likelihood that global containment standards can be met and successfully maintained.

STRATEGY

The global strategy for minimizing poliovirus facility-associated risks consists of risk elimination by destroying poliovirus materials in all but certified poliovirus-essential facilities[1] and biorisk management of these facilities by strict adherence to required safeguards.

Risk elimination

Risk elimination in poliovirus-non-essential facilities is achieved through the destruction, or transfer to poliovirus-essential facilities, of:

1. infectious and potentially infectious WPV materials;
2. OPV/Sabin materials, as described below.

Destruction applies to all materials potentially contaminated with any type or strain of WPV or OPV/Sabin poliovirus, or where the presence of polioviruses cannot be ruled out, particularly with regard to untested virus stocks in facilities that in the past worked with polioviruses (9) and in non-polio facilities retaining valuable clinical materials potentially infected with polio or OPV/Sabin viruses.

Successful global elimination of the risk requires each country to effectively prohibit retention and subsequent acquisition of poliovirus materials in all poliovirus-non-essential facilities following global recommendations (3).

Biorisk management

Biorisk management in designated poliovirus-essential facilities (Annexes 2 and 3) is achieved through the implementation of international biorisk management standards that:

1. include polio-specific containment requirements to reduce the likelihood of release of polioviruses from poliovirus-essential facilities (primary safeguards);
2. describe population immunity requirements (secondary safeguards) to minimize the consequences of the release of polioviruses from poliovirus-essential facilities;
3. define the site-specific environmental requirements for poliovirus-essential facilities (tertiary safeguards), to further minimize the consequences of release.

Primary safeguards of containment reduce the likelihood of accidental or malicious poliovirus release from a poliovirus-essential facility and are specified in the "Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials" (Annex 2) and "Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no WPV)" (Annex 3). Key elements include:

- facility management, which practises continuous risk assessment and strict observance of biosafety and laboratory biosecurity procedures;
- the containment facility, which incorporates appropriate design, construction and operation principles, addressing identified biorisk;
- the immunization of facility personnel, which can reduce the risk of infection in the facility and intra- or extra-household transmission, should infection occur (10; 11);
- reduction in the use of WPV and the substitution with Sabin strains or further attenuated strains where possible (10);

[1] Laboratories or polio vaccine production facilities.

- contingency plans for potential virus release or exposure, which specify actions and assign responsibilities for the facility, the institution, the ministry of health (MoH) and other concerned government agencies.

Secondary safeguards of population immunity minimize the consequences of a poliovirus release into the community from a poliovirus-essential facility and consist of a national routine childhood polio immunization policy and the achievement of high national population coverage consistent with WHO policy (3) and eventual post-eradication strategies (12).

Tertiary safeguards of facility location minimize the consequences of the unintentional release of highly transmissible WPV by placing poliovirus-essential facilities in areas with demonstrated low poliovirus R_0, i.e. in areas with closed sewage systems with a minimum of secondary treatment of effluents.

Primary and secondary safeguards are required for poliovirus-essential facilities that handle and store WPV2 or OPV2/Sabin2 materials during the poliovirus type 2 containment period and after cessation of bOPV use (Table 1). The potential for spread (R_0) is two to 10 times less for Sabin/OPV strains than for WPV, which reduces the risk for infection at the community level if a breach of containment occurs, and the consequences of such a breach if transmission were recognized in time (11).

Primary, secondary and tertiary safeguards are required for poliovirus-essential facilities that handle and store WPV materials after WPV eradication (Table 1).

National certification and regular annual recertification thereafter is required for all poliovirus-essential facilities. WHO verification of compliance with GAPIII may be requested on a regular (triennial) basis. National certification supported by WHO verification provides assurance that the required safeguards are met.

Table 1: GAPIII containment safeguards at a glance

	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
1° safeguards: Prevent infection & release of contaminated materials			
Operator protection[2]	Yes	Yes	Yes
Decontamination of materials/equipment	Yes	Yes	Yes
Dedicated effluent treatment plant	No[3]	No[3]	Yes[4]
Air/exhaust treatment	No	No	Yes[5]
2° safeguards: Population immunity in country hosting the facility			
IPV doses	≥ 1	≥ 1	≥ 3
IPV coverage	= DTP3 coverage[6]	= DTP3 coverage	>90%[7]
3° safeguards: Environment & location			
Siting of facilities in areas with low transmission potential (R_0) for wild polioviruses	No	No	Yes

DTP3: Diphtheria–tetanus–pertussis vaccine third dose.

[2] Since the operator is considered to be one of the sources of poliovirus release from the facility, specific protection measures are required, including, for example, the use of personal protective equipment (PPE), the use of primary containment devices and vaccination.

[3] Untreated release into a closed sewage system with secondary effluent treatment in the facility location (all waste from facilities, potentially containing live poliovirus, should be inactivated prior to release through adequate and validated inactivation procedures. In facilities without a dedicated effluent treatment plant, this would normally be done by applying heat or chemicals as part of a validated treatment process. Under no circumstances should raw poliovirus containing effluents be discharged to drains, unless the effluent treatment plant has been designed and validated to handle such effluents, effectively acting as part of the primary containment system).

[4] Facility effluent treatment before release into a closed sewage system with secondary or greater effluent treatment in the facility location.

[5] High-efficiency particulate arresting (HEPA) filtration on exhaust air.

[6] Diphtheria–tetanus–pertussis vaccine third dose (DTP3) immunization coverage (19).

[7] Global Vaccine Action Plan 2011–2020 (20).

OVERVIEW OF PHASES

The Global Action Plan is implemented in three phases linked to national and international milestones in polio eradication (Figure 1).

Phase I: Preparation for containment of poliovirus type 2

Phase I is in progress until the conditions for global readiness of OPV2 withdrawal have been met.

Key activities

- conducting national laboratory survey and poliovirus type 2 inventory;
- destroying unneeded poliovirus type 2 materials;
- transferring needed poliovirus type 2 materials to poliovirus-essential facilities;
- informing governments, institutions and polio facilities about the upcoming need for poliovirus containment;
- certifying designated poliovirus-essential facilities for containment.

Phase II: Poliovirus type 2 containment period

Phase II commences as soon as the criteria for global readiness of OPV2 withdrawal are met, and continues until certification of global WPV eradication. Readiness criteria (13) for OPV2 withdrawal include:

1. the introduction of at least one dose of IPV in routine immunization;
2. access to a bOPV that is licensed for routine immunization;
3. the implementation of surveillance and response protocols for type 2 poliovirus (including constitution of a stockpile of mOPV2);
4. the completion of Phase I poliovirus containment activities, with appropriate handling of residual type 2 materials;
5. the verification of global eradication of WPV2.

The trigger for setting a definite date for global OPV2 withdrawal (tOPV-bOPV switch) will be the absence of all persistent cVDPV2 for at least six months.

This phase has two parts, addressing the containment of WPV2 or OPV2/Sabin2:

Phase IIa: Containment of WPV2

- All WPV2 are contained (as per Table 1 and Figure 1) in certified poliovirus-essential facilities (Annex 2).

Phase IIb: Containment of OPV2/Sabin2 poliovirus

- All OPV2/Sabin2 polioviruses are contained (as per Table 1 and Figure 1) in certified poliovirus-essential facilities (Annex 3).

Phase IIb commences within three months of OPV2 withdrawal (tOPV-bOPV switch).
During Phase II, action on OPV2/Sabin2 poliovirus containment may be temporarily suspended in areas where a decision by WHO has been made to use mOPV2 to respond to emerging or re-emerging WPV2/cVDPV2 transmission.

Phase III: Final poliovirus containment

Phase III commences when global WPV transmission has not been detected for three years and just prior to the certification of global WPV eradication.

Phase IIIa: Final containment of all WPV

- All WPV is contained long term (as per Table 1 and Figure 1) in certified poliovirus-essential facilities, with enhanced primary safeguards.

Phase IIIb: Final containment of all OPV/Sabin polioviruses

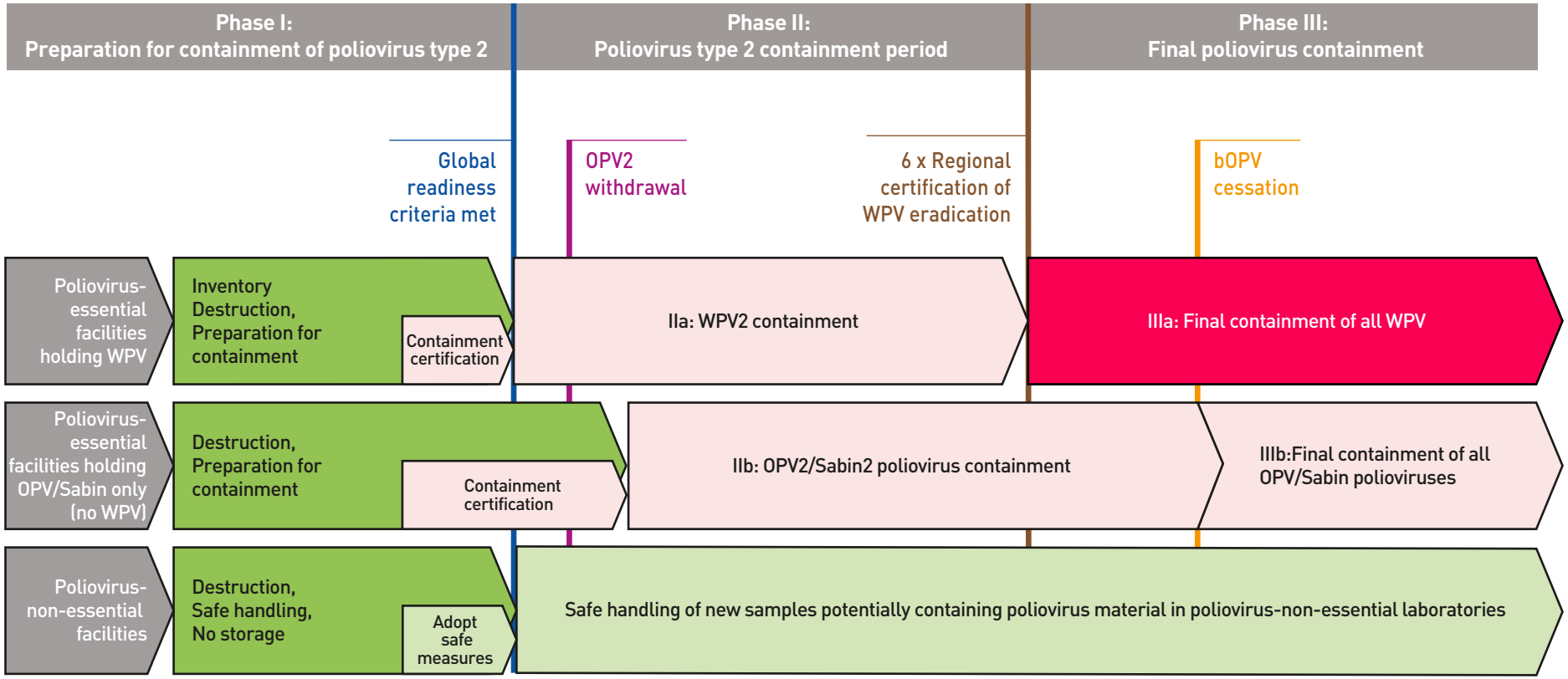
- All OPV/Sabin polioviruses are contained long term (as per Table 1 and Figure 1) in certified poliovirus-essential facilities.

Phase IIIb commences within three months of bOPV cessation (bOPV cessation is planned one year after the certification of global WPV eradication).

During phase III, action on OPV/Sabin poliovirus containment may be temporarily suspended in areas where a decision by WHO has been made to use mOPV to respond to emerging or re-emerging WPV/cVDPV transmission.

The implementation requirements for the different phases are described below.

Figure 1: Containment requirements



- No containment
- Adoption of safe-handling measures
- Containment of WPV2, OPV2/Sabin2; Final containment of all OPV/Sabin polioviruses
- Final containment of all WPV

Global readiness criteria for OPV2 withdrawal:

1. **IPV:** Introduction of at least one dose of IPV;
2. **bOPV:** Access to a bivalent oral polio vaccine that is licensed for routine immunization;
3. **Surveillance and Stockpile:** Implementation of surveillance and response protocols for type 2 poliovirus (including constitution of a stockpile of mOPV2);
4. **Containment:** Completion of Phase I poliovirus containment activities, with appropriate handling of residual type 2 materials;
5. **Verification:** Verification of global eradication of WPV2.

Trigger for setting a date for the withdrawal of OPV2:

Absence of all persistent cVDPV2

6 x Regional certification of WPV eradication:

The Regional Certification Commissions (RCC) will certify their regions as polio-free once WPV transmission is interrupted in that region, i.e. 36 months after the last WPV is detected.

PHASE IMPLEMENTATION

Phase I: Preparation for containment of poliovirus type 2

Phase I: Inventory, destruction, preparation for poliovirus type 2 containment

During Phase I, countries shall:

- survey all biomedical facilities to identify those with infectious or potentially infectious WPV materials and encourage the destruction of all unneeded materials. The survey starts with the establishment of a national database of biomedical facilities that includes all facilities with the following types of laboratories: poliovirus/enterovirus, general virology, clinical bacteriology, parasitology, environmental and industrial (polio vaccine and general microbiological filter and disinfectant manufacturers), or any other laboratory handling and storing polioviruses. Facilities listed in the database are surveyed to confirm whether WPV infectious or potentially infectious materials are being stored;

- develop a national inventory of facilities that handle and store WPV materials, and report to the Regional Certification Commission (RCC) for poliomyelitis eradication. The national inventory serves as a current record of poliovirus facilities. National inventories are assembled into regional inventories maintained by WHO regional offices;

- submit annual reports to the RCC on the current status of the national inventory of facilities with poliovirus materials;

- complete national surveys and inventories, and submit documentation to the RCC that the Phase I survey and inventory requirements have been met. The MoH submits the complete report on Phase I survey and inventory activities and supporting documents to the National Certification Committee for review and endorsement before submission to the RCC.

After completion of national surveys and inventories and in preparation for Phase II, all countries shall:

- adopt international goals (3) for the timely destruction or containment of WPV2 materials and of OPV2/Sabin2 materials, and decide to either:
  - prohibit the retention of all GAPIII-specified poliovirus materials by any facility after achieving specific milestones, or
  - prohibit the retention of all GAPIII-specified poliovirus materials except in designated certified poliovirus-essential facilities.

Countries considering the need for poliovirus-essential containment facilities shall weigh the risks and benefits of such facilities in consultation with all relevant ministries (e.g. health, education, defence, environment, etc.) and the responsibilities inherent in complying with the crucial primary, secondary and tertiary safeguards. They will:

- alert biomedical facilities to national policies/international agreements (14) pertaining to the retention of WPV materials or OPV/Sabin materials to permit the orderly planning for compliance;

- instruct facilities that work or have worked with poliovirus, enteroviruses, rhinovirus, rotavirus or norovirus to confirm the identity of all virus stocks, reference strains and derivatives of such viruses grown in poliovirus-permissive cell cultures to rule out the presence of poliovirus (10). Where and when necessary, virus stocks of uncertain histories or multiple passages must be replaced with stocks of documented authenticity from an international culture collection or from other investigators using appropriate reference techniques. Laboratories wishing to retain historic collections of clinical materials shall explore options with designated poliovirus-essential research and reference facilities for handling and storage arrangements;

- request facilities on the national inventory submit plans for compliance with poliovirus retention policies and/or regulations (14), including the status of materials and action timelines;

- request poliovirus-non-essential facilities that do not intend to retain infectious or potentially infectious poliovirus materials (6) to:
  - destroy unneeded poliovirus material (WPV infectious and potentially infectious materials, and any OPV/Sabin materials), or
  - transfer all needed poliovirus type 2 material to poliovirus-essential facilities;

- request poliovirus-non-essential laboratory facilities that as of Phase II are likely to investigate new WPV2, aVDPV2, cVDPV2 or iVDPV2 isolates, or new faecal or respiratory samples originating from recent OPV-using countries, to adopt and implement:
  - safe and secure working practices based on a risk assessment and the implementation of appropriate biorisk management systems (Annex 6)
  - a non-retention policy for WPV2 materials as of the beginning of Phase IIa of the poliovirus type 2 containment period
  - a non-retention policy for OPV2/Sabin2 materials as of the beginning of Phase IIb of the poliovirus type 2 containment period;

  If poliovirus type 2 is isolated after the initiation of Phase IIa, the facility must immediately notify the MoH and WHO, and transfer the isolate to a designated certified poliovirus-essential facility;

- notify the general biomedical laboratory community that, according to the globally endorsed Endgame Strategy (3), the retention of WPV2 materials will no longer be permitted in Phase IIa and the retention of OPV2/Sabin2 materials will no longer be permitted in Phase IIb, except in designated certified poliovirus-essential facilities. Facilities are fully responsible for compliance with national policies and/or regulations (14), including the destruction of WPV2 infectious and potentially infectious materials and any OPV2/Sabin2 materials or the transfer of such materials to a designated poliovirus-essential facility. Facilities in the national database of biomedical laboratories with a history of performing activities placing them at risk of having potentially infectious poliovirus materials or contaminated stocks must respond to the MoH or another designated national authority documenting the absence of such materials.

Countries with plans to designate poliovirus-essential facilities shall in addition:

- request candidate facilities assess and submit documentation demonstrating compliance with secondary and tertiary safeguards, as applicable to the type of material being held (WPV2 or OPV2/Sabin2 poliovirus);

- implement national certification procedures to assess the compliance of poliovirus-essential facilities with the "Containment of poliovirus type 2" provisions, including primary and secondary safeguards. Designated poliovirus-essential facilities wishing to handle and store WPV2 materials must be fully certified before Phase II;

- establish national contingency plans for responding to the potential release of or exposure to poliovirus (15);

- request candidate poliovirus-essential facilities[8] that plan to handle and store infectious WPV2 materials be certified in the implementation of the "Containment of poliovirus type 2" provisions, including primary and secondary safeguards (Annex 2), before Phase II. If unable to meet the requirements, all WPV2 materials must be transferred to a country and facility meeting the requirements, or be destroyed;

- request candidate poliovirus-essential facilities[9] that plan to handle and store only OPV2/Sabin2 materials (but no WPV2) be certified in the implementation of the "Containment of OPV2/Sabin2 poliovirus" provisions, including primary and secondary safeguards (Annex 3), no later than three months after the switch. If unable to meet the requirements, all OPV2/Sabin2 materials must be transferred to a country and facility meeting the requirements, or be destroyed.

  Countries or concerned facilities may apply through their national authorities for WHO verification of poliovirus-essential facilities, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 2 or 3 (Annex 4).

Preparing for the tOPV-bOPV switch

- The WHA resolution (14) on the tOPV-bOPV switch (16) provides details on the process for implementing each step leading to OPV2 withdrawal, the recall of unused tOPV and the containment of OPV2/Sabin2 polioviruses:
  - tOPV-using countries shall respond to the WHA resolution (14) with detailed plans for compliance.
  - All countries shall review or expand the Phase I institution or facility database to include new or other biomedical laboratories that might have infectious or potentially infectious OPV2/Sabin2 materials of any origin. (Physicians' offices, pharmacies and health facilities that may have tOPV vials will be notified through other government channels as part of the tOPV-bOPV switch process).
  - Plans and actions to prepare for the tOPV-bOPV switch continue in Phase II as described below.

[8] Laboratories or IPV production facilities.
[9] Laboratories or OPV/Sabin-IPV production facilities.

Phase II: Poliovirus type 2 containment period

Phase IIa: Containment of WPV2

Phase IIa commences when the criteria for global readiness of OPV2 withdrawal are met.

As of the beginning of Phase IIa:

- The handling and storage of WPV2 material are no longer permitted in poliovirus-non-essential facilities.

- Poliovirus-non-essential laboratory facilities that are likely to investigate new WPV2, aVDPV2, cVDPV2 or iVDPV2 isolates, or new faecal and respiratory samples originating from recent OPV-using countries must:
  - implement safe and secure working practices based on a risk assessment and appropriate biorisk management systems (Annex 6);
  - not retain any WPV2 materials for long-term storage;
  - immediately destroy any newly isolated WPV2 materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

- Certified poliovirus-essential facilities[10] handling and storing WPV2 in Phase II must implement and be regularly (e.g. annually) reassessed against the "Containment of poliovirus type 2" provisions, including primary and secondary safeguards, as described in Annex 2. Facilities that have not yet received formal national certification in the containment of poliovirus type 2 are no longer allowed to handle and store WPV2 materials.

- Countries or concerned facilities may apply through their national authorities for WHO verification of poliovirus-essential WPV2-holding facilities, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 2 (Annex 4).

Phase IIb: Containment of OPV2/Sabin2 poliovirus

Moving forward with the preparations for the tOPV-bOPV switch:

- All countries shall notify the general laboratory community of forthcoming requirements for the implementation of the "Containment of OPV2/Sabin2 poliovirus" provisions. The general laboratory community already is, or should be, aware of pending actions linked to the tOPV-bOPV switch. Facilities shall be reminded in writing of the planned date for the tOPV-bOPV switch and that national policies and regulations (14) pertaining to OPV2/Sabin2 poliovirus destruction or containment will be in force at that time. Communications from the MoH or another designated national authority to all biomedical laboratory facilities shall further encourage the destruction of unneeded OPV/Sabin materials. Laboratories wishing to maintain access to historic collections of clinical materials potentially infectious for OPV2/Sabin2 polioviruses shall explore options with designated certified poliovirus-essential research and reference containment facilities for handling and storage arrangements.

[10] Laboratories or IPV production facilities.

Global tOPV administration will stop (OPV2 cessation) at an effective date established by the World Health Assembly (14).

At the effective date for the tOPV-bOPV switch (OPV2 cessation), all countries must:

- recall and destroy tOPV stocks. WHO will provide specific implementation guidelines (16) for the collection and destruction of tOPV from designated collection points, health facilities or private practitioners, and national and subnational storage facilities.

  Phase II coincides with a period of intense VDPV surveillance and elimination. Some high-risk areas may require the emergency use of mOPV2 to respond to emerging or re-emerging VDPV2 transmission. In such areas it may be necessary to temporarily suspend the "Containment of OPV2/Sabin2 poliovirus" provisions, until the emergency is resolved.

Within six months of the switch, all countries must:

- submit documentation to the RCC that the containment of OPV2/Sabin2 poliovirus requirements have been met.

Phase IIb commences three months after the global tOPV-bOPV switch.

As of the beginning of Phase IIb (within three months of the switch):

- The handling and storage of OPV2/Sabin2 poliovirus material are no longer permitted in poliovirus-non-essential facilities.

- Poliovirus-non-essential laboratory facilities that are likely to investigate new faecal and respiratory samples originating from recent OPV-using countries must:
  - implement safe and secure working practices based on a risk assessment and appropriate biorisk management systems (Annex 6);
  - not retain any WPV2 or OPV2/Sabin2 materials for long-term storage;
  - immediately destroy any newly isolated type 2 poliovirus materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

- Certified poliovirus-essential facilities[11] handling and storing only OPV2/Sabin2 polioviruses (but no WPV2) must implement and be regularly (e.g. annually) reassessed against the "Containment of OPV2/Sabin2 poliovirus" provisions, including primary and secondary safeguards, as described in Annex 3. Sabin virus stocks of uncertain histories or multiple passages must be replaced with stocks of documented authenticity from an international culture collection or from other investigators using appropriate reference techniques to rule out possible contamination with WPV. Facilities that have not yet received formal national certification in the containment of OPV2/Sabin2 poliovirus are no longer allowed to handle and store OPV2/Sabin2 poliovirus materials.

[11] Laboratories or OPV/Sabin-IPV production facilities.

The storage of mOPV2 stockpiles (frozen bulk and finished product, prepared in accordance with international requirements (15)) and the replenishment of mOPV2 stockpiles of filled vaccine vials must be performed under appropriate containment conditions, based on a risk assessment approved by the competent authority.

- Countries or concerned facilities may apply through their national authorities for WHO verification of poliovirus-essential facilities holding OPV2/Sabin2, certified by the MoH or another designated national authority, and declared to meet all biorisk management criteria consistent with Annex 3 (Annex 4).

Preparing for Phase III

In preparation for Phase IIIa (Final containment of all WPV), countries with poliovirus-essential facilities holding WPV shall in addition:

- implement national certification procedures to assess compliance with the "Final containment of all WPV" provisions, including primary, secondary and tertiary safeguards;

- request poliovirus-essential facilities[12] that plan to handle and store infectious WPV materials in Phase III be certified and regularly (e.g. annually) reassessed against the "Final containment of all WPV" implementation provisions, including primary, secondary and tertiary safeguards (Annex 2) before Phase III. Facilities failing national certification will have to discontinue WPV activities until deficiencies are satisfactorily corrected and national certification is granted. If unable to meet the requirements, all WPV materials must be destroyed or transferred to a country and facility meeting the requirements before Phase III.

  Nationally certified poliovirus-essential facilities holding WPV may be verified through WHO (Annex 4).

In preparation for Phase IIIb (Final containment of all OPV/Sabin polioviruses), countries with poliovirus-essential facilities holding OPV/Sabin shall in addition:

- implement national certification procedures to assess compliance with the "Final containment of all OPV/Sabin polioviruses" provisions, including primary and secondary safeguards;

- request poliovirus-essential facilities[13] that plan to handle and store OPV/Sabin or infectious Sabin-derived materials (but no WPV) in Phase III be certified and regularly (e.g. annually) reassessed against the "Final containment of all OPV/Sabin polioviruses" implementation provisions, including primary and secondary safeguards (Annex 3) before bOPV cessation. Facilities failing national certification will have to discontinue OPV/Sabin poliovirus activities until deficiencies are satisfactorily corrected and national certification is granted. If unable to meet the requirements, all OPV/Sabin poliovirus materials must be destroyed or transferred to a country and facility meeting the requirements before bOPV cessation.

[12] Laboratories or Salk-IPV production facilities.
[13] Laboratories, Sabin-IPV production, or OPV stockpile facilities.

Nationally certified poliovirus-essential facilities holding OPV/Sabin polio virus materials may be verified through WHO (Annex 4).

Within three months of the declaration of interruption of all WPV transmission, all countries must:

- submit documentation to the relevant WHO RCC that the requirements for the destruction or risk management of WPV materials in Phase II have been met.

Phase III: Final poliovirus containment

Phase IIIa: Final containment of all WPV

Phase IIIa commences when all six WHO regions have completed the certification of WPV eradication, three years after the isolation of the last WPV.

As of the beginning of Phase IIIa, certified poliovirus-essential laboratories and IPV production facilities handling and storing WPV materials must:

- implement the "Final containment of all WPV" provisions, including primary, secondary and tertiary safeguards, as described in Annex 2. Facilities that have not yet received formal national certification in the final containment of all WPV are no longer allowed to handle and store WPV materials.

Countries with poliovirus-essential facilities holding WPV shall continue to:

- implement national certification procedures to regularly (annually) assess the compliance of WPV-holding facilities with the "Final containment of all WPV" provisions, including primary, secondary and tertiary safeguards;

- request certified poliovirus-essential facilities[14] that handle and store WPV materials in Phase III be regularly (e.g. annually) reassessed against the "Final containment of all WPV" implementation provisions, including primary, secondary and tertiary safeguards (Annex 2), in order to confirm their certification status. If unable to meet the requirements, all WPV materials must be destroyed or transferred to a country and facility meeting the requirements.

  Nationally certified poliovirus-essential facilities may be verified through WHO (Annex 4).

Phase IIIb: Final containment of all OPV/Sabin polioviruses

Global bOPV cessation is planned one year after the global declaration of WPV eradication.

[14] Laboratories or IPV productions facilities.

At the effective date, all countries must:

- recall and destroy bOPV stocks. WHO will provide specific implementation guidelines for the collection and destruction of bOPV from designated collection points, health facilities or private practitioners, and national and subnational storage facilities.

Phase IIIb commences three months after global bOPV cessation.

As of the beginning of Phase IIIb, certified poliovirus-essential laboratories and Sabin-IPV production facilities handling and storing OPV/Sabin materials (but no WPV) must:

- implement the "Final containment of all OPV/Sabin polioviruses" provisions, including primary and secondary safeguards, as described in Annex 3. Facilities that have not yet received formal national certification in the final containment of all OPV/Sabin polioviruses are no longer allowed to handle and store OPV/Sabin materials.

Countries with poliovirus-essential facilities holding OPV/Sabin materials shall continue to:

- implement national certification procedures to regularly (annually) assess the compliance of OPV/Sabin-holding facilities with the "Final containment of all OPV/Sabin polioviruses" provisions, including primary and secondary safeguards;

- request certified poliovirus-essential facilities[15] that handle and store OPV/Sabin or Sabin-derived materials (but no WPV) in Phase III be regularly (e.g. annually) reassessed against the "Final containment of all OPV/Sabin polioviruses" implementation provisions, including primary and secondary safeguards (Annex 3), in order to confirm their certification status. If unable to meet the requirements, all OPV/Sabin materials must be destroyed or transferred to a country and facility meeting the requirements.

  The storage of mOPV stockpiles (frozen bulk and finished product, prepared in accordance with international requirements (15)) and the replenishment of mOPV stockpiles of filled vaccine vials must be performed under appropriate containment conditions, based on a risk assessment approved by the competent authority.

  Nationally certified poliovirus-essential facilities may be verified through WHO (Annex 4).

Within six months of bOPV cessation, all countries must:

- submit documentation to the RCC that the requirements for the final containment of all OPV/Sabin polioviruses have been met.

[15] Laboratories, Sabin-IPV production, or OPV stockpile facilities.

Table 2: Phased implementation of poliovirus containment

Pre-requisites	Phase	Begins	Target completion date	Key activities
Phase I: Preparation for containment of poliovirus type 2				
	I: Inventory, destruction, preparation for poliovirus type 2 containment	Ongoing	Global readiness of OPV2 withdrawal	**Inventory, destruction, preparation for poliovirus type 2 containment:** • survey/inventory facilities that are handling or storing infectious or potentially infectious poliovirus materials. Poliovirus-non-essential facilities: • destroy unneeded poliovirus material; • transfer needed poliovirus type 2 material to poliovirus-essential facilities; • adopt a non-retention policy for new WPV2/Sabin2 isolates, to be implemented as of Phase IIa. Poliovirus-essential facilities: • obtain national certification.
Phase II: Poliovirus type 2 containment period				
Elimination of WPV2 Elimination of persistent cVDPV2	**IIa: WPV2 containment**	Global readiness of OPV2 withdrawal	6 x regional certification of WPV eradication	**Containment of WPV2** Certified poliovirus-essential WPV2-holding laboratories and IPV production facilities: • handle and store WPV2 materials according to the "Containment of WPV2" provisions. Poliovirus-non-essential facilities: • destroy the remaining unneeded Sabin2 material; • transfer needed Sabin2 material to certified poliovirus-essential facilities. Poliovirus-non-essential facilities investigating new WPV2, aVDPV2, cVDPV2 or iVDPV2 isolates, or new faecal and respiratory samples originating from recent OPV-using countries: • implement a non-retention policy; • destroy unneeded recently isolated poliovirus material; • transfer needed recently isolated poliovirus material to certified poliovirus-essential facilities.

Pre-requisites	Phase	Begins	Target completion date	Key activities
Licensed and available bOPV Global introduction of IPV Global tOPV-bOPV switch	**IIb: OPV2/ Sabin2 poliovirus containment (post-tOPV-bOPV switch)**	Within three months of global tOPV-bOPV switch	Within three months of global bOPV cessation (bOPV cessation is planned one year after global certification of WPV eradication)	**Containment of OPV2/Sabin2 poliovirus** Certified poliovirus-essential OPV2/ Sabin2-holding laboratories or OPV/ Sabin-IPV production facilities: • handle and store OPV2/Sabin2 materials according to the "Containment of OPV2/ Sabin2 poliovirus" provisions.
Phase III: Final poliovirus containment				
Three years after isolation of last WPV	**IIIa: Post-eradication**	6 x regional certification of WPV eradication	Long-term eradication (beyond global bOPV cessation)	**Final containment of all WPV** Certified poliovirus-essential WPV-holding laboratories or IPV production facilities: • handle and store all WPV materials according to "Final containment of all WPV" provisions.
Global bOPV cessation	**IIIb: Post-bOPV cessation**	Within three months of global bOPV cessation (bOPV cessation is currently planned one year after global certification of WPV eradication)	Long-term eradication (beyond global bOPV cessation)	**Final containment of all OPV/Sabin polioviruses** Certified poliovirus-essential OPV/ Sabin-holding laboratories or Sabin-IPV production facilities: • handle and store OPV/Sabin materials according to the "Final containment of all OPV/Sabin polioviruses" provisions.

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ANNEXES

ANNEX 1

Definitions

These definitions apply to the terms as used in this report; the words may have different meanings in other contexts.

Aerosol: A dispersion of solid or liquid particles of microscopic size in a gaseous medium.

Audit: The systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Biological safety cabinets: Class II and Class III cabinets that are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens. Class II cabinets for microbiological work are partially open-fronted enclosures with air drawn around the operator into the front grille and a downward laminar flow of HEPA-filtered air that provide product protection by minimizing the chance of cross-contamination along the work surfaces of the cabinet. Class III cabinets are gas-tight enclosures with a non-opening view window, allowing access into the cabinet through a dunk tank or double-door pass-through box that is decontaminated between uses. Both supply and exhaust air are HEPA filtered or incinerated before discharge. Airflow is maintained under negative pressure.

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

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

Biosecurity, laboratory: 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.

$CCID_{50}$: A cell culture infectious dose that will infect 50% of the cell monolayers challenged with the defined inoculum.

Calibration: The correlation of the readings of an instrument with a standard.

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

- National certification to this standard is expected to be performed once a year through responsible national oversight bodies.

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

Contingency planning: The preparation for a future event or circumstance regarded as likely to occur, or as influencing present action.

Decontamination: A procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects.

Diagnosis: The analysis of samples for the purpose of identifying or confirming the presence of a specific agent.

Disinfection: The process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms.

Facility: Any laboratory 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, certifiable: A facility approved by the ministry of health or another designated national body or authority as a qualified applicant for national containment certification.

Facility, poliovirus-essential: 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 infectious materials or potentially infectious materials under conditions set out in this standard.

Fumigation: The process whereby one or more chemicals are applied in the gaseous state to an enclosed space for the purpose of decontaminating the area and the items therein.

Global Certification Commission (GCC): The term commonly used to refer to the Global Commission for the Certification of the Eradication of Poliomyelitis, which has responsibility to define the parameters and processes by which polio eradication will be certified, receive and review reports of the regional commissions, and issue a final report to the Director-General of WHO certifying that global polio eradication has been achieved.

Good microbiological techniques: Technical methods designed to avoid or minimize the most common causes of laboratory injuries or work-related infections (See WHO Laboratory biosafety manual, Third edition, 2004, http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf).

Guidelines: Principles or criteria guiding or directing action.

Hazard: Any source, situation or act with potential for causing harm.

High-efficiency particulate arresting or high-efficiency particulate air (HEPA) filter: A filter capable of removing at least 99.97% of all particles with a mean aerodynamic diameter of 0.3 micrometres.

Inactivation: Rendering an organism inert by the application of heat or other means.

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

Legislation: The process of making laws.

National Certification Committee: The term commonly used to refer to a country's National Committee for the Certification of the Eradication of Poliomyelitis, which is responsible for certifying to the Regional Certification Commission that eradication has been achieved throughout the country.

Needed poliovirus materials: Poliovirus materials deemed needed and worth storing to ensure the continuation of critical international functions, including Salk-IPV and Sabin-IPV production, the development and storage of oral polio vaccine stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, and crucial research.

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

Penetrations: Openings through walls, floors or ceilings to allow for mechanical services.

Policy: The course or principle of action adopted or proposed by the responsible government entity.

Poliovirus: A picornavirus consisting of three serotypes: 1, 2 and 3. Poliovirus serotypes are further subdivided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines). Polioviruses use CD155 as the primary cellular receptor.

Poliovirus, wild:

- Wild polioviruses are naturally occurring isolates known or believed to have circulated persistently in the community.
- Vaccine-derived polioviruses (VDPV) are classified with wild polioviruses and usually demonstrate 1–15%[16] sequence differences from the parental oral polio vaccine (OPV) strain; they may have circulated in the community (cVDPV) or have replicated for prolonged periods in immunodeficient subjects (iVDPV) or be ambiguous and of unknown origin (aVDPV).
- Attenuated strains not licensed for use as live vaccines (Cox/Lederle and Koprowski/Wistar series) are classified with wild polioviruses as their clinical properties are unproven.

Wild poliovirus materials may be (a) infectious or (b) potentially infectious.

(a) Poliovirus infectious materials, wild: These include:

- clinical materials from confirmed wild poliovirus (including VDPV) infections;
- environmental sewage or water samples that have tested positive for the presence of wild polioviruses;
- cell culture isolates and reference strains of wild poliovirus;
- seed stocks and infectious materials from IPV production;

[16] Some isolates display >15% sequence diversity but are phylogenetically related to parental Sabin strains.

- infected animals or samples from such animals, including human poliovirus receptor transgenic mice;
- derivatives produced in the laboratory that have capsid sequences from wild polioviruses, unless demonstrably proven to be safer than Sabin strains. The safety of new derivatives containing wild poliovirus capsid sequences will be assessed by an expert panel, on the basis of comparison to reference Sabin strains for (i) degree and stability of attenuation; (ii) potential for person-to-person transmission; and (iii) neurovirulence in animal models;
- full-length RNA or cDNA that includes capsid sequences derived from wild poliovirus, unless viruses derived from them are demonstrably proven to be safer than Sabin strains. The safety of full-length RNA or cDNA containing wild poliovirus capsid sequences will be assessed by an expert panel convened by WHO, on the basis of comparison to reference Sabin strains for (i) degree and stability of attenuation; (ii) potential for person-to-person transmission; and (iii) neurovirulence in animal models;
- cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus.

(b) Poliovirus potentially infectious materials, wild: These include:

- faecal or respiratory secretion samples collected for any purpose in a time and geographic area of wild poliovirus (including VDPV) circulation;
- products of such materials from poliovirus permissive cells or animals;
- uncharacterized enterovirus-like cell culture isolates from countries known or suspected to have circulating wild poliovirus or VDPV at the time of collection;
- respiratory and enteric virus stocks handled under conditions where poliovirus contamination or replication is possible.

Poliovirus, Sabin (OPV/Sabin strains)**:** Attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains).

Poliovirus, OPV-like: For the laboratory network not involved in manufacture, isolates consistent with a limited period of virus excretion or person-to-person transmission, demonstrating less than 1% difference from parent OPV strains for poliovirus types 1 and 3, and less than 0.6% difference from the type 2 parent OPV strain by full Viral Protein 1 sequence homology. The phenotype of clinical and environmental OPV-like isolates need not be determined as the great majority are assumed to be of low virulence.

Sabin materials may be (a) infectious or (b) potentially infectious. The attenuated phenotype of viruses resulting from manufacture based on the OPV/Sabin seeds must be assured and cannot rely on the lack of sequence drift alone.

(a) Poliovirus infectious materials, OPV/Sabin: These include:

- cell culture isolates and reference OPV/Sabin strains;
- seed stocks and live virus materials from OPV production;
- environmental sewage or water samples that have tested positive for the presence of OPV/Sabin strains;
- faecal or respiratory secretion samples from recent OPV recipients;
- infected animals or samples from such animals, including poliovirus receptor transgenic mice;
- derivatives produced in the laboratory that have capsid sequences from OPV/Sabin strains;

- full-length RNA or cDNA that includes capsid sequences derived from OPV/Sabin strains;
- cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains.

(b) Poliovirus potentially infectious materials, OPV/Sabin: These include:

- faecal or respiratory secretion samples collected for any purpose in a time and geographic area of OPV use;
- products of such materials from poliovirus permissive cells or animals;
- respiratory and enteric virus stocks handled under conditions where OPV/Sabin strain contamination or replication is possible.

Regional Certification Commission (RCC): The term commonly used to refer to the Regional Commission for the Certification of the Eradication of Poliomyelitis, which has been established in each of the six WHO regions with responsibility to certify to the GCC that eradication has been achieved throughout all Member States of their region.

Regulation: Government action to control by rule or subject to restrictions.

Reproductive rate (R_0): A measure of the transmissibility of a pathogen that captures community vulnerability and virus characteristics calculated as the number of secondary infections caused by a single index case in an entirely susceptible population.

Risk: A combination of the probability of the occurrence of harm and the severity of that harm.

Risk assessment: A qualitative or semi-qualitative process undertaken by individuals with expertise in appropriate disciplines and backgrounds in response to an identified hazard.

Safeguards, primary: Containment precautions and stipulations designed to minimize the facility-associated poliovirus risks of exposing and/or infecting populations.

Safeguards, secondary: The population immunity profile consistent with minimizing the consequence of a poliovirus release from a poliovirus-essential containment facility, consisting of a national routine childhood immunization policy and high (>90%) national population coverage.

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.

Senior Manager (SM): The official representative of an institution with overall authority and accountability for ensuring the biosafety management of the facility.

Sharps: Devices used in the facility that are capable of cutting and/or puncturing skin (e.g. needles, scissors, glass).

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.

Sterilization: A process that destroys and/or removes microorganisms and their spores.

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.

- WHO verification of compliance with this standard may be requested for certified poliovirus-essential facilities (14).

ANNEX 2

Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials

Introduction

A facility-associated poliovirus infection or release into the environment during the Endgame Strategy period and following eradication and cessation of oral polio vaccine (OPV) use will be a public health event of international proportions. The *Global Action Plan* addresses that risk by establishing a post-eradication/post-OPV cessation goal of retaining poliovirus in a limited number of poliovirus-essential facilities worldwide. The *Global Action Plan* further reduces the risk posed by these facilities by establishing international standards for primary safeguards of facility containment, secondary safeguards of population immunity, and tertiary safeguards of facility location and assurance through national and international oversight that such standards are met.

Primary safeguards minimize the risk of facility-associated poliovirus release and include facility management; the design and operation of the containment facility; practices and procedures; the vaccination of facility personnel and their close family members; and contingency plans for potential virus release or exposure. Secondary safeguards of population immunity minimize the consequence of a poliovirus release from a poliovirus-essential containment facility and consist of a national routine childhood immunization policy and demonstrated high (=DTP3; >90%) national population coverage (12). Tertiary safeguards of facility location minimize the risk of transmissible poliovirus by placing such facilities in areas with closed sewage systems with secondary or greater effluent treatment in areas with low transmission potential (R_0) for wild polioviruses. Primary and secondary safeguards are required for poliovirus-essential facilities handling and storing wild poliovirus type 2 (WPV2) in the poliovirus type 2 containment period. Primary, secondary and tertiary safeguards are required for poliovirus-essential facilities that are handling and storing any WPV materials in the final containment phase.

This "Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials" describes the international requirements for the primary safeguards established for poliovirus-essential laboratories handling and storing WPV materials or for Salk-IPV production facilities. This standard is based on CWA15793, *Laboratory biorisk management* (2), the principles of the WHO *Laboratory biosafety manual, Third edition* (17) and the extensive poliovirus scientific literature spanning nearly seven decades (10). This standard serves as the framework for national certification and WHO verification (Annex 4). It consists of 16 elements and subelements based on the principles of a quality management system. It assumes that the organization is best placed to understand the risks associated with its work and can manage those risks in a number of ways acceptable to the national and international bodies responsible for facility oversight. This standard further assumes that poliovirus-essential facility personnel and management at all levels fully appreciate the enormity of the consequences of accidental or malicious poliovirus release in the post eradication/post - OPV era and are prepared to demonstrate that the appropriate systems and controls are in place to manage those risks.

Poliovirus facility-associated risks

Polioviruses under moist conditions in clinical or environmental samples can survive indefinitely in the laboratory freezer (<-20 °C), for many months in the refrigerator and for weeks on the bench top at ambient temperatures (18). Infectivity is inactivated by dehydration, heat (>50 °C) or treatment with dilute solutions of formaldehyde or bleach at appropriate concentrations.

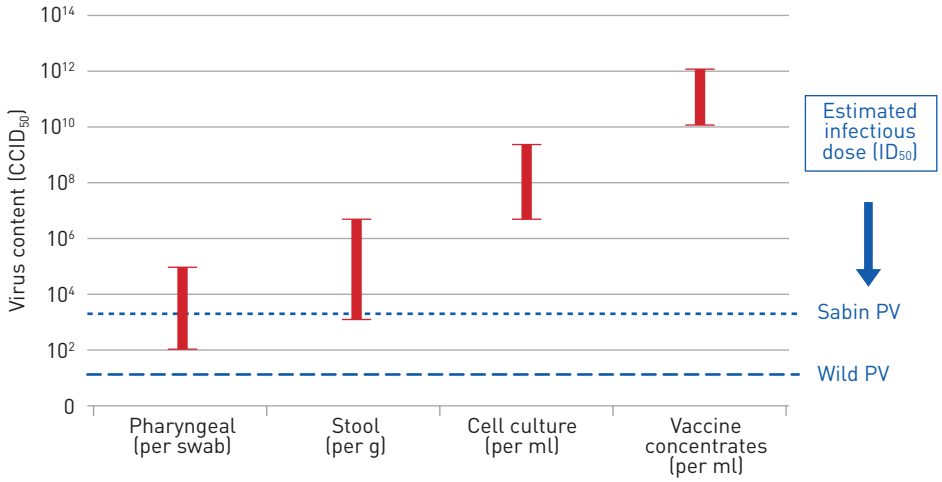
The most common routes of exposure to infectious agents in the facility environment are (1) ingestion; (2) inhalation; (3) injection; and (4) contaminated skin and mucous membranes. The infectious dose is a factor of virus virulence, the route of presentation and virus particles in sufficient number to overcome mechanical loss and natural and immune host defences. In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/g (Sabin) to $10^{4.3}$ $CCID_{50}$/g (wild) in stool samples, to10^{8} $CCID_{50}$/ml in cell culture harvests, and 10^{11} $CCID_{50}$/ml in concentrates in vaccine production facilities. Sabin strains are less pathogenic than wild and have lower secondary infection rates, but all three Sabin virus types have been linked to vaccine-derived poliovirus (VDPV) outbreaks.

Ingestion presents the highest risk for facility personnel. Immunization with OPV or inactivated polio vaccine (IPV) prevents disease, but neither fully inhibits silent poliovirus infection nor reinfection of the gut. Ingestion of poliovirus may result from any laboratory operation, activity or incident that leads to the transfer of infectious particles to the gastrointestinal tract. Estimated infectious doses (ID_{50}) by ingestion, based on studies with infants and children, are $\pm10^{1}$ $CCID_{50}$ for wild polioviruses and $\pm10^{3}$ $CCID_{50}$ for Sabin strains. Immunized adult laboratory workers are likely more resistant than immunologically naïve children, but resistance is dose related and may be overcome by ingesting sufficient poliovirus particles. Droplets created by sprays, spills and the splash of poliovirus cell cultures (10^{8} $CCID_{50}$) and concentrates (10^{11} $CCID_{50}$) constitute the highest personnel exposure risks (Figure A2.1).

Inhalation, defined as exposure to small particle aerosols of <5 micrometres (μm) (droplet nuclei) deposited predominately in the lower respiratory tract, has been identified as a possible route of infection for poliovirus. The respiratory tract appears not to be a significant portal of entry. Unresolved, however, is whether small particle aerosols deposited in the lower respiratory tract may initiate alimentary tract infections through mucociliary transport

to the pharyngeal region. Inhalation risks may be further reduced in facility environments maintained at low relative humidity (<50%). Antibodies acquired through immunization greatly reduce infection risks from injection or breaks in skin or mucous membranes.

Figure A2.1: Estimated poliovirus content and infectious dose[17]



Community members may be exposed to infectious agents from the laboratory through (1) workers' contaminated skin or clothing or unrecognized infection; (2) the release of contaminated air; (3) contaminated effluents and waste water recovered from secondary sewage treatment plants; (4) the uncontrolled transport of infectious material; (5) solid waste transported to landfills; (6) contaminated equipment or materials removed from the facility; (7) the escape of infected animals; and (8) a theft or deliberate release of infectious agents from a facility. Exposure risks through routes 4-7 are low for poliovirus facilities that adhere to international regulations for the transport of infectious substances, those outlined in the *Good Laboratory Practice* handbook and the WHO guidelines on *Good Manufacturing Practice*, and likely low for the inhalation of contaminated air effluent where facilities maintain low relative humidity environments and exhaust air away from direct human exposure. Exposure risks through the ingestion of effluents range between high and low, depending on the poliovirus content of facility effluent, sewerage system size and integrity, and the potential for human consumption. Risks of community exposure are highest through facility personnel unknowingly contaminated or infected with poliovirus. IPV immunization of facility personnel may greatly reduce the risk of intra- and extra-household transmission.

Effective poliovirus risk management is achieved by the careful assessment of exposure risks, the implementation of risk-appropriate personnel protection measures, and the quality operation of a facility designed to minimize the risk of poliovirus contamination and dissemination to the community. The main risk is the infection of laboratory workers by ingestion. Airborne transmission is conceivable but not demonstrated and infection through parenteral exposure such as needlestick is unlikely in immunized individuals.

[17] Estimated infectious doses (ID_{50}) are based on studies with infants and children. Immunized adult laboratory workers are likely much more resistant than immunologically naïve children. However, dose-related resistance may be overcome by ingesting sufficient poliovirus particles.

MANAGEMENT SYSTEM ELEMENTS

Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials

CWA15793 Clause No.[18]	Biorisk Management Element No.	Requirements for Containment of WPV2	Requirements for Final Containment of all WPV	Guidance
		Element 1 – Biorisk Management System The biorisk management system element examines the system and policy in place to manage laboratory biorisk. Effective management and organization are vital to the success of any activity, and management commitment and leadership lay the foundation upon which a solid biorisk management system is built. Management must have clear strategies and objectives from which roles and responsibilities are allocated, implemented and monitored. Without effective management commitment and appropriate organizational structures, all other initiatives aimed at managing risk will be ineffective. The way management thinks and acts has a major impact on performance. **Subelements** 1.1 Biorisk Management Policy 1.2 Objectives, Targets and Programme 1.3 Roles, Responsibilities and Authorities 1.4 Records, Documents and Data Control 1.5 Analysis of Data 1.6 Change Management 1.7 Consultation and Communication 1.8 Programme of Work 1.9 Work Planning and Capacity 1.10 Legal Requirements 1.11 Continual Improvement 1.12 Preventive Action 1.13 Control of Nonconformities 1.14 Inspection and Audit 1.15 Corrective Action 1.16 Contractors and Suppliers 1.17 Biorisk Management Review 1.18 Biorisk Management System		

[18] Clause numbers referenced from final CWA15793, 2011 published version.

CWA15793 Clause No.[18]	Biorisk Management Element No.	Requirements for Containment of WPV2	Requirements for Final Containment of all WPV	Guidance
	1	**BIORISK MANAGEMENT SYSTEM**		
	1.1	**Biorisk Management Policy**		
CWA 4.2.1	1.1.1	Actions taken by top management demonstrating commitment to the policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity) include: 1. development; 2. authorization; 3. signing.		Biorisk management should be stated clearly as part of the organization's health, safety, security and environment (HSE) policies. Depending on the relevance of biorisk management to the organization, the biorisk management policy should complement the general HSE policies. As appropriate, the biorisk management policy may be integrated into the organization's HSE policies.
CWA 4.2.1	1.1.2	The policy clearly states: 1. the overall biorisk management objectives; 2. a commitment to improving biorisk management performance.		The policy should require that all projects/work areas be assessed for risks and a full assessment be prepared before approval is given to commence work.
CWA 4.2.1	1.1.3	The policy is appropriate to the nature and scale of the risk associated with the facility and associated activities.		
CWA 4.2.1	1.1.4	The policy commits to: 1. protecting staff, contractors, visitors, the community and the environment from poliovirus materials that are stored or handled within the facility; 2. reducing the risk of the unintentional release of, or exposure to, poliovirus materials; 3. reducing the risk of the unauthorized intentional release of hazardous biological materials to an acceptable level; 4. complying with all legal requirements applicable to the poliovirus materials that will be handled or possessed, and with the requirements of this standard; 5. ensuring that the need for effective biorisk management takes precedence over all non-"health and safety" operational requirements; 6. informing all employees and relevant third parties effectively and communicating individual obligations with regard to biorisk to these groups; 7. improving biorisk management performance continually.		The policy includes the need to conduct risk assessments and implement the required control measures.

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	1.2	**Objectives, Targets and Programme**		
CWA 4.3.3.1	1.2.1	Documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization are: 1. established; 2. implemented; 3. maintained.		
CWA 4.3.3.2	1.2.2	Management has established the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.		The controls can be monitored by regular audits, by utilizing corrective-action reporting processes where problems have been identified, by investigating incidents and accidents and improving controls and their implementation, and by ensuring adequate resources are provided to maintain the effectiveness of the controls. Note: Refer to Element 2 – Risk Assessment.
	1.3	**Roles, Responsibilities and Authorities**		
CWA 4.4.1.1	1.3.1	Top management takes ultimate responsibility for the organization's biorisk management system.		Top management includes officers (Director-General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and directors of the organization. Overall responsibility for managing biorisk rests with top management but tasks may be delegated through the organization, provided they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller organizations, one individual may hold more than one role described in this standard. It is important to define roles and responsibilities, have clear communication within the organization regarding actions that need to be taken, and establish who has the required authority.
CWA 4.4.1.1	1.3.2	Top management ensures that roles, responsibilities and authority related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of polioviruses.		In assigning roles and responsibilities, potential conflicts of interest should be considered.

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				This standard has identified roles that need to be covered in the organization and has only used titles to illustrate these roles; these titles may not be the same as those used in specific organizations.
CWA 4.4.1.1	1.3.3	Top management demonstrates its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.		Resources include human resources and specialized skills, organizational infrastructure, technology and financial resources.
CWA 4.4.1.2	1.3.4	A senior manager has been designated with the operational responsibility to oversee the biorisk management system.		Senior managers are those with significant operational, budgetary and personnel authority at the departmental or higher level, and may include members of top management.
CWA 4.4.1.2	1.3.5	The senior manager's functions in managing biorisk include: 1. providing appropriate resources to ensure the adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; 2. reporting to top management on the performance of the biorisk management system and any need for improvement; 3. ensuring the promotion of the biorisk management system throughout the organization; 4. instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.		The senior management representative should be an individual with decision-making authority at a level whereby he/she can allocate resources and make decisions regarding the facility's biorisk management needs (including required resources to conduct risk assessments and other management and administrative activities) independently of the need to implement the programme of work.
CWA 4.4.1.3	1.3.6	A biorisk management committee has been constituted to act as an independent review group for biorisk issues associated with the poliovirus facility.		The biorisk management committee is often recognized as the institutional biosafety committee. Its role may be either a dedicated function or one that is addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management adviser(s), the security manager and the occupational health professional. Others, such as the facility manager and/or worker and community representatives, may be included depending on the nature of the agenda or work.

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CWA 4.4.1.3	1.3.7	The biorisk management committee reports to senior management and: 1. has documented terms of reference; 2. includes a representative cross section of expertise, appropriate to the nature and scale of the activities undertaken; 3. ensures issues addressed are formally recorded, and actions are allocated, tracked and closed out effectively; 4. is chaired by a senior individual; 5. meets at a defined and appropriate frequency, and when otherwise required.		The committee's functions should include: a. contributing to the development of institutional biorisk policies and codes of practice; b. approving proposals for new work or significant modifications to the potential risk associated with existing activities; c. reviewing and approving protocols and risk assessments for work involving polioviruses; d. reviewing information related to significant accidents or incidents, data trends, associated local or organizational actions and communication needs. The list of roles for the biorisk management committee is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.4	1.3.8	One or more competent individuals are designated to provide advice and guidance on biorisk management issues.		The competent individual providing advice and guidance on biorisk management is often recognized as a biological safety officer or biological safety adviser. This function should normally be regarded as an advisory position and not one directly responsible for managing biorisk, as that rests with those conducting and managing the work within the organization (e.g. the scientific director, principal investigator, department head, laboratory manager, group leader). The role and knowledge of the biorisk adviser are important to develop, implement, maintain and continually improve a biosafety and biosecurity programme based on a management system. The adviser should be competent to perform the role and be allocated sufficient time and other resources to do the job effectively.
CWA 4.4.1.4	1.3.9	The biorisk management adviser's role is independent of the functions of those responsible for implementing the programme of work.		In the execution of their biorisk management duties, advisers should be independent from those responsible for implementing the programme of work and have direct access to the top management representative when necessary.

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CWA 4.4.1.4	1.3.10	The biorisk management adviser: 1. reports directly to the responsible senior manager; 2. has delegated authority to stop work in the event that it is considered necessary to do so.		The biorisk management adviser's functions should include: a. verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed; b. advising or participating in the reporting, investigation and follow-up of accidents/incidents and, where appropriate, referring these to management and/or the biorisk management committee; c. ensuring relevant and up-to-date information and advice on biorisk management are made available to scientific and other personnel as necessary; d. advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security); e. contributing to the development and/or delivery of biorisk training activities; f. ensuring all relevant activities are performed in compliance with biorisk regulations, and the required biorisk authorizations for work are in place. The list of roles for the biorisk management adviser is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.5	1.3.11	One or more individuals with responsibility for the scientific programme within the facility have been designated with responsibilities relevant to biorisk management.		The scientific manager is responsible for managing the scientific programme within the facility on a day-to-day basis, and for implementing and monitoring biorisk controls in association with other facility personnel (e.g. adhering to policies and procedures, monitoring staff performance and participation in inspections and audits). The individual would normally have an in-depth knowledge of the work programme and the facility, would be in a supervisory/management position and may be referred

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				to as Head of Department, Principal Investigator, Laboratory Supervisor/Manager or Group Leader. Competence is required in technical/scientific aspects of the poliovirus materials being used and in their control, and in the management of the facility, its personnel and systems. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.5	1.3.12	The scientific management functions include: 1. ensuring all work is conducted according to established policies and guidelines described in this standard; 2. supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; 3. planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; 4. ensuring required authorizations for work are in place; 5. ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and the required control measures are in place; 6. ensuring all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).		
CWA 4.4.1.6	1.3.13	The organization has access to appropriate occupational health expertise.		The occupational health professional would normally be a medical doctor or occupational health nurse with an understanding of the poliovirus materials handled within the facility. The role should include providing input into risk assessment from a worker's health perspective, advising on first aid/ emergency treatment measures and follow-up, liaising with external health-care providers, and coordinating medical examinations, surveillance and vaccination programmes.

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				The occupational health professional's roles and responsibilities should be determined in light of requirements set out in this standard.
CWA 4.4.1.6	1.3.14	The organization has established an occupational health programme commensurate with the facility's activities and risks.		
CWA 4.4.1.7	1.3.15	One or more facility managers have been appointed with responsibilities relevant to facilities and equipment, determined according to requirements set out in this polio biorisk management standard.		The facility manager would normally be an engineer or a person with an in-depth knowledge of laboratory facilities, containment equipment and buildings. The role should include providing input into risk assessment from a facility perspective, coordinating building and maintenance work, and liaising with contractors. The roles and responsibilities of the facility management personnel should be determined in light of requirements set out in this standard. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.8	1.3.16	A security manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.		The security manager would normally have an in-depth knowledge of laboratory and facility security, should liaise with other personnel (e.g. the biorisk management adviser) and implement effective and proportionate laboratory biosecurity measures, based on the biological risk. The role should include providing input into risk assessment and management from a security perspective. The security personnel's roles and responsibilities should be determined in light of requirements set out in this standard.
CWA 4.4.1.9	1.3.17	In laboratories where animals are kept, an animal-care manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.		The animal-care manager would normally have an in-depth knowledge of animal handling, and zoonotic and animal diseases. The animal-care manager should liaise with other personnel (e.g. biorisk management adviser, occupational health professional) to implement effective and proportionate laboratory biosafety and biosecurity measures. A qualified veterinarian

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				should be available for additional advice. The role should include providing input into risk assessment and management from an animal-care perspective.
	1.4	**Records, Documents and Data Control**		
CWA 4.5.2	1.4.1	Records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this polio biorisk management standard.		Where appropriate, documents should be identified and controlled based on the nature of the work and need for record-keeping.
CWA 4.5.2	1.4.2	Records, documents and data are handled in such a way that they remain legible, readily identifiable and retrievable. Documented records are maintained in paper or electronic form for a minimum of 10 years from the day of withdrawal and should be available for review during national certification/WHO verification procedures.		Controlled documents may include: a. risk assessments, standard operating procedures (SOPs) and safety manuals; b. job hazard analyses and charts of authority; c. design records and commissioning/test plans, maintenance plans and records, and all associated data; d. audit and inspection checklists; e. laboratory biosecurity manuals and risk assessments, authorizations and other security documents; f. training records; g. containment equipment certifications. The list of controlled documents is not exhaustive but includes some of the main areas that should be formally recorded and subject to document control. Data should be construed as documents in this context. A procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention period and disposal of records. A procedure should be established to define the controls needed for the approval of documents prior to their issue or public release, to ensure sensitive information such as the specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define

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				the controls needed for the review, update and reapproval of documents, and for the control of change and revision process.
	1.5	**Analysis of Data**		
CWA 4.5.1	1.5.1	Appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.		The analysis should include data generated as a result of monitoring, measurement, audits and analysis, and from other sources. Such analyses should be conducted at least annually, and more often if justified by the risks and scope of operations. The results of the analysis should be applied in the management review.
	1.6	**Change Management**		
CWA 4.4.4.4	1.6.1	All changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.		These changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include an evaluation of the effect of the changes on the risk assessment. Examples of changes that should be subject to the change management process include: a. modifications to buildings and equipment or their operation, which could or would have an effect on biorisk; b. introduction of altered staffing arrangements (such as the temporary presence of on-site contractors or students, temporary reassignments of personnel); c. changes to the programme of work, including alterations to workflow or volume, which could or would have an effect on biorisk; d. alterations to SOPs, including significant changes in materials or reagents; e. modifications to entry/exit protocols; f. modifications to personnel policies and visitor protocols;

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				g. modifications to disinfection, decontamination and other waste management methodologies; h. changes associated with the provision and use of personal protective equipment (PPE).
	1.7	**Consultation and Communication**		
CWA 4.4.4.3	1.7.1	Relevant biorisk information related to an organization's activities is communicated to and from employees and other relevant parties.		The organization should implement mechanisms to ensure relevant and current information that can potentially affect workers and others is defined and delivered effectively at appropriate intervals. This could entail regular team meetings and briefings in the workplace, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others, including: a. local, national and international governmental organizations; b. relevant regulatory agencies; c. certifiers; d. emergency services and health-care providers; e. contractors and suppliers (e.g. cleaners, maintenance providers, security personnel); f. local community representatives (e.g. through a community liaison committee). Systems should be put in place to identify existing or emerging technologies or other relevant information related to the containment of the poliovirus materials being handled or stored. This information should be shared with relevant staff through appropriate media, including the circulation of appropriate signage, documents and team briefings, and the maintenance of reference libraries and other sources of information.
CWA 4.4.3	1.7.2	Employee involvement and consultation arrangements are documented.		

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CWA 4.4.3	1.7.3	Personnel have access to adequate and up-to-date information about the organization's biorisks.		
	1.8	**Programme of Work**		
CWA 4.4.4.3	1.8.1	The programme of work for the facility is defined, documented and reviewed.		The programme should include the nature of the activities authorized to be conducted in the facility and their definitions (e.g. diagnostics, research, small scale/large scale). All activities associated with the work programme should be specified and supported by formal SOPs approved in line with the requirements for controlled documents, as defined by this standard. Any changes to the programme of work should be subject to a formal change management process.
CWA 4.4.4.3	1.8.2	Criteria are established for work that requires prior approval.		
	1.9	**Work Planning and Capacity**		
CWA 4.4.4.3	1.9.1	Sufficient resource capacity and capability are available to manage workflow, whether planned or unplanned.		The resources needed to implement and maintain the biorisk management system and continually improve its effectiveness should be determined and provided.
	1.10	**Legal Requirements**		
CWA 4.3.2	1.10.1	The organization ensures that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national/federal, regional/state, provincial, city and local regulations with which the organization must comply.		The organization should adopt measures to identify the facility's legal and other requirements related to the poliovirus materials to be held and used, but also to other regulations including, for example, worker protection and rights, environmental impact, and general health and safety (e.g. fire, electrical). Monitoring for new and upcoming requirements, as well as those that already exist, is needed. This information should be kept up to date and the requirements should be incorporated into the facility's biorisk management system.
	1.11	**Continual Improvement**		

CWA15793 Clause No.[18]	Biorisk Management Element No.	Requirements for Containment of WPV2	Requirements for Final Containment of all WPV	Guidance
CWA 4.1.2	1.11.1	The organization continually improves the effectiveness of the biorisk management system through: • the policy; • its objectives; • the self-audit programme; • audit results; • the analysis of data; • the risk assessment; • corrective and preventive actions; • the management review.		The organization should strive to continue developing and refining the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved by setting objectives and giving targets to those working within the facility and by monitoring progress to ensure the objectives are achieved.
	1.12	**Preventive Action**		
CWA 4.5.4.4	1.12.1	Action is taken to identify and eliminate the causes of potential nonconformities to prevent their occurrence.		A procedure should be established to define requirements for: a. determining the potential nonconformities and their causes; b. evaluating the need for action to prevent the occurrence of nonconformities; c. determining and implementing the action needed; d. recording the results of action taken; e. reviewing the preventive actions taken.
CWA 4.5.4.4	1.12.2	Preventive actions are appropriate to the effects of the potential nonconformities.		
	1.13	**Control of Nonconformities**		
CWA 4.5.4.2	1.13.1	Situations that do not conform to the requirements of this polio biorisk management standard are identified and controlled to prevent undesirable consequences.		The controls and related responsibilities and authorities needed to deal with nonconforming situations should be defined in a procedure.
CWA 4.5.4.2	1.13.2	Records are maintained of the nature of the nonconformity and any subsequent action taken.		
	1.14	**Inspection and Audit**		

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CWA 4.5.5	1.14.1	An inspection and audit programme is conducted that is appropriate to the risk associated with the facility.		Inspections may be frequent checks of specific areas, conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels/concentrations, air exchange rates/ maintenance of directional air flow), or may be more extensive but less frequent inspections of laboratories, facilities or other operations. Random, unannounced inspections and inventory audits can help ensure compliance at all times and not just in time for scheduled inspections. Audits should be performed by competent individuals unaffiliated with the audited activity. Records of inspection/audit findings should be maintained, including action taken to close out any nonconformities or pursue improvement opportunities.
CWA 4.5.5	1.14.2	Inspections and audits are conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and the requirements of this polio biorisk management standard, and if it is effectively implemented and maintained. *National inspection and audit.* An inspection and audit programme is conducted regularly (e.g. annually) by national authorities to determine if the biorisk management system conforms to the requirements of this standard and is functioning properly, and to ensure necessary corrective actions are taken and verified without undue delay. *WHO inspection and audit.* Top management ensures that information is made available in English according to WHO review team needs, that it is accessible for the periodic comprehensive WHO review of the poliovirus facility and that deficiencies identified by the process, as outlined in 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)*, are addressed to the satisfaction of WHO.		

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CWA 4.5.5	1.14.3	Management responsible for the area being inspected/audited ensures that any actions are taken without undue delay to eliminate detected nonconformities and their causes.		
CWA 4.5.5	1.14.4	Follow-up activities include: 1. verification of the actions taken; 2. reporting of the verification results.		
	1.15	**Corrective Action**		
CWA 4.5.4.3	1.15.1	To prevent the recurrence of any nonconformities, action is taken to eliminate their causes using the requirements of the polio biorisk management standard for *poliovirus-essential facilities holding wild poliovirus materials.*		A procedure should be established to define requirements for: a. reviewing the nonconformities; b. determining the cause of nonconformities; c. evaluating the need for action to ensure nonconformities do not recur; d. determining and implementing the action needed; e. recording the results of action taken; f. reviewing the corrective actions taken.
CWA 4.5.4.3	1.15.2	Corrective actions are appropriate to the effects of the nonconformities encountered.		
	1.16	**Contractors and Suppliers**		
CWA 4.4.4.8.6	1.16.1	Purchases (including services) conform to specified requirements.		
CWA 4.4.4.8.6	1.16.2	Controls on purchases (including services) are applied depending on the potential impact on the biorisk involved.		
CWA 4.4.4.8.6	1.16.3	Suppliers are evaluated and selected based on their ability to provide products/services that meet the requirements of this polio biorisk management standard.		While not all suppliers will provide products/services that may have an impact on biorisk, many may. Suppliers that should be considered include, but are not limited to, those that provide: a. cleaning services; b. laboratory equipment; c. waste management or disposal services; d. information technology support services;

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				e. equipment and facility maintenance services; f. security services.
CWA 4.4.4.8.6	1.16.4	Criteria for selection, evaluation and re-evaluation are established.		
CWA 4.4.4.8.6	1.16.5	Records are maintained of evaluation results and any necessary actions arising from the evaluation.		
	1.17	**Biorisk Management Review**		
CWA 4.6.1	1.17.1	Top management reviews the organization's biorisk management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness.		The management review should be conducted regularly, at a frequency determined by the needs of the organization, but at least annually.
CWA 4.6.1	1.17.2	The review includes: 1. assessing opportunities for improvement; 2. determining the need for changes to the system, procedures, policies and objectives.		Review input should include information on: a. the results of audits; b. compliance with SOPs and work instructions; c. the status of risk assessment activities; d. the status of preventive and corrective actions; e. follow-up actions from previous management reviews; f. changes that could affect the system; g. recommendations for improvement; h. the results of accident/incident investigations.
CWA 4.6.1	1.17.3	Records are maintained from the management review.		The review's output should include decisions and actions related to: a. improvement of the biorisk management system's effectiveness; b. improvement related to the requirements and risk assessments; c. resource needs.
	1.18	**Biorisk Management System**		
CWA 4.1.1	1.18.1	The organization has established, documented, implemented and maintains a biorisk management system according to the requirements of this polio biorisk management standard.		

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		Element 2 – Risk Assessment The Risk Assessment element looks at how organizations define risk and implement effective mechanisms to identify, assess and manage those risks. Areas addressed include how to ensure consistency and transparency in assessing risk across the organization, without placing an unnecessary burden on specialists and support staff. This element is regarded as a foundation upon which the others must be based. **Subelements** 2.1 Process, Methodologies and Procedures 2.2 Assessment Timing and Scope 2.3 Roles and Responsibilities 2.4 Hazard Identification 2.5 Risk Assessment 2.6 Risk Control		
	2	**RISK ASSESSMENT**		
	2.1	**Process, Methodologies and Procedures**		
CWA 4.3.1.1	2.1.1	The organization ensures that a risk assessment system is established, implemented and maintained according to this polio biorisk management standard.		
CWA 4.3.1.1	2.1.2	The risk management system's performance is reported to senior management for review and as a basis for improvement.		
CWA 4.4.4	2.1.3	The organization has identified those operations and activities associated with possible biological risk and where control measures are to be applied.		
CWA 4.4.4	2.1.4	Activities associated with possible biological risk, including maintenance, are carried out under specified conditions.		
	2.2	**Assessment Timing and Scope**		

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CWA 4.3.1.2	2.2.1	The approach to risk assessment is defined according to its scope, nature and timing so it is proactive rather than reactive.		The following should trigger either a new risk assessment or the review of an existing one: a. commencement of new work or changes to the programme of work, including the introduction of new biological agents or alterations to workflow or volume; b. new construction/modifications to laboratories, plants and equipment or their operation; c. introduction of altered and unplanned staffing arrangements, including those concerning contractors, visitors and other non-core personnel; d. significant alterations to SOPs or working practices (e.g. disinfection/waste management methodologies, PPE provision, usage entry, exit protocols); e. unexpected events that may be relevant to the management of biorisks; f. actual or potential nonconformity with internal/external rules and regulations (e.g. the introduction of new legislation or major accident exposure); g. consideration of emergency response and contingency planning requirements; h. the existing management system review process (e.g. annually or at another appropriate and predetermined frequency). Many defined methodologies and approaches are available to conduct hazard identification, risk assessment and control; the approach taken will vary depending on the nature of the situation and the level of detail required. One framework that organizations may consider adopting is outlined in Figure 1 of CWA15793, 2011 (GAPIII, Annex 5).
	2.3	**Roles and Responsibilities**		

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CWA 4.3.1.1	2.3.1	Resource requirements have been identified and adequate resources provided, including assigning trained personnel to management, work performance and verification activities, including internal review.		The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need the organizational freedom and authority to: a. initiate action to prevent or reduce the adverse effects of risk; b. control the further treatment of risks until the level of risk becomes acceptable; c. identify and record any problems related to managing risks; d. initiate, recommend or provide solutions through designated channels; e. communicate and consult internally and externally as appropriate.
	2.4	**Hazard Identification**		
CWA 4.3.1.3	2.4.1	The hazards associated with proposed work are: 1. identified; 2. documented.		The first stage in the risk management process is to identify all hazards relevant to biorisk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and risk management. A hazard may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting) or a material (in this case, the principal hazard is most likely to be a poliovirus, but others include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is its potential to cause harm, regardless of how likely such an occurrence might be. Biological hazards should be identified and assessed in relation to their potential damage to humans, animals and the environment. Where hazardous materials are classified into hazard or risk groups based on international and/or foreign

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				country classification schemes, local diverging needs and constraints should be considered. A hazard identification exercise should use information that includes: a. group experience and knowledge; b. external or specialized expertise not found in the facility; c. results of previous assessments; d. surveys of previous accidents/incidents; e. hazardous materials data; f. information on hazardous organisms; g. guidelines and codes of practice; h. facility drawings; i. SOPs, manuals, etc.; j. process maps. Defined methodologies and approaches are available to conduct hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and its activities. Hazard identification should be appropriate in nature and structure, and recorded to a level whereby others can review the process.
	2.5	**Risk Assessment**		
CWA 4.3.1.4	2.5.1	Suitable methodologies for assessing and recording risks are: 1. identified; 2. implemented; 3. maintained. Risk assessments are documented.		The risk assessment should categorize risks to identify those that need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels, should be defined and used in the assessment. Such a classification can be achieved, for example, by using a risk matrix that identifies likelihood and consequence categories,

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				ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate. Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. In conducting the assessment, due consideration should be given to the inherent risk from polioviruses (e.g. from risk grouping descriptions, material safety data sheets). After defining and implementing control measures, the risks should be reviewed to decide whether the remaining risk is acceptable or additional controls need to be identified and implemented.
	2.6	**Risk Control**		
CWA 4.3.1.5.	2.6.1	Suitable methodologies for allocating actions that result from risk assessments, including timelines, responsible persons and associated reporting and approval mechanisms, are: 1. identified; 2. implemented; 3. maintained.		The risk management approach should have a control plan that includes: a. who is responsible and accountable for implementing the plan; b. what resources are to be used (e.g. people, budget); c. a timetable for implementation; d. details of the mechanism and frequency of reviewing compliance with the plan. Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls or the reliance on PPE.
		Element 3 – Poliovirus Inventory and Information The Poliovirus Inventory and Information element examines the systems in place to identify, record and review the organisms stored, received and transported from a facility. The level of detail and nature of the system		

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		depends on the pathogens being held, and ranges in complexity from simple lists to secure databases. This element also examines the way materials are stored, including segregation, labelling systems and controls of stocks of cultures. **Subelements** 3.1 Inventory 3.2 Information and Records 3.3 Transfer of Poliovirus Materials 3.4 Monitoring and Control		
	3	**POLIOVIRUS INVENTORY AND INFORMATION**		
	3.1	**Inventory**		
CWA 4.4.4.2	3.1.1	An accurate and up-to-date poliovirus inventory is established and maintained.		The inventory process should be based on risk and include: a. identifying all poliovirus materials held, including cultures, specimens and other sources (e.g. infected tissues/samples or animals); b. storing poliovirus material within the containment perimeter of the poliovirus facility, ensuring stored samples of wild and Sabin poliovirus materials are segregated from each other and other isolates, cell lines, cultures or other materials that could be subject to cross-contamination or misidentification; c. ensuring the movement of poliovirus materials to and from storage meets the standards of element 15 (Transport Procedures); d. ensuring the surfaces of all storage vessels are decontaminated with a validated method for inactivating polioviruses; e. restricting access to poliovirus materials to authorized individuals with a demonstrable legitimate need; f. implementing effective physical security measures according to risk (e.g. locks, alarms, access controls);

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				g. developing and maintaining a reliable sample identification system; h. segregating and storing poliovirus materials according to risk; i. determining what materials should be controlled (e.g. seed stocks, working stocks, infected animals) and what level of information should be captured in the inventory for these materials.
	3.2	**Information and Records**		
CWA 4.4.4.2	3.2.1	Records related to the poliovirus inventory are: 1. current; 2. complete; 3. stored securely with adequate backup provision.		Inventory information should include: a. the name(s) and contact information of the individuals(s) responsible for the poliovirus material, and the details of other personnel with access to the poliovirus materials or the immediate area based on the level of risk; b. restricted access to the detailed inventory records to those individuals whose work requires access to that information; c. legible and robust identification numbers and other relevant identifiers; d. records of quantities/volumes of poliovirus materials at an appropriate level and based on risk (number of containers/vials or applicable equivalent), exact location of storage, and ability to account for materials at all times; e. origin, including geographical source and date of collection; f. records of materials removed from storage to conduct work, and the fate of those materials and any newly developed stocks (consumed, destroyed, removed from the facility, returned to storage in location X) following the completion of the work.
	3.3	**Transfer of Poliovirus Materials**		
CWA 4.4.4.2	3.3.1	Transfers of poliovirus materials between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of risk.		Controls should be put in place to ensure all the necessary checks and documented assurances are received to guarantee

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				that requests for poliovirus materials originate from legitimate facilities and individuals. Material may only be brought into the facility or sent elsewhere if authorized by those responsible for the facility. For materials deemed to be of high risk, more stringent controls, including shipment tracking and the verification of receipt, are necessary.
	3.4	**Monitoring and Control**		
CWA 4.5.3	3.4.1	The inventory is reviewed at predetermined intervals based on risk, and at a level and frequency whereby materials can be accounted for in an appropriate manner.		The nature of the inventory and associated controls should be based on the nature of the material held and on the risk of harm should it be misplaced or removed with the intention of misuse. Poliovirus inventories will be monitored so that materials missing, unaccounted for or no longer needed are identified, consistent with the goal of reducing amounts of live poliovirus materials to the lowest level possible. An inventory review will be conducted at least annually.
CWA 4.5.3	3.4.2	Measures are put in place to minimize the quantities of poliovirus materials in the inventory.		The organization should demonstrate proactive measures to reduce risk through the elimination, substitution or minimization of volumes/quantities of poliovirus materials used, and the number of manipulations conducted. Procedures should be in place to investigate potentially missing poliovirus materials.
		Element 4 – General Safety The General Safety element examines the processes in place to make sure hazards associated with the personnel's work in the facility are identified and managed while addressing their implications for biorisk. Both a preventive and proactive approach should be taken to establish measures to identify, detect, mitigate and respond to emergencies related to general safety, such as fire, electricals, radiation, chemicals, animal care and pressurized equipment.		

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		Subelement 4.1 General Safety		
	4	**GENERAL SAFETY**		
	4.1	**General Safety**		
CWA 4.4.4.1	4.1.1	A formal process is in place to identify and manage risk associated with general safety.		The organization should adopt a preventive and a proactive approach to managing such sources of risk, both to protect workers from the direct hazards associated with their work and to address the implications for biorisk in the event of an accident/ incident resulting from such sources. Measures should be identified and implemented to detect, mitigate and respond to emergencies, taking into consideration the potential implications for poliovirus control in such measures. Issues addressed should include but are not limited to: a. general laboratory safety; b. fire safety; c. electrical safety; d. radiation safety; e. chemical safety; f. the use of gasses (including risk of asphyxiation); g. hot work and cold work; h. equipment under pressure; i. laboratory animal care and use; j. general housekeeping, including storage requirements and tidiness, and the control of general waste.
		Element 5 – Personnel and Competency The Personnel and Competency element covers the processes in place to ensure that people with appropriate qualifications and backgrounds are recruited, that they are subsequently trained in all aspects of the work programme, and that their competency is assessed and monitored in a		

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		structured way. Other issues dealt with include how capacity issues are addressed and staff turnover is managed to ensure the organization is not left vulnerable when critical roles are vacated. **Subelements** 5.1 Recruitment 5.2 Training 5.3 Competence 5.4 Continuity and Succession Planning 5.5 Exclusion		
	5	**PERSONNEL AND COMPETENCY**		
	5.1	**Recruitment**		
CWA 4.4.2.1	5.1.1	Qualifications, experience and aptitudes related to biorisk are considered as part of the recruitment process.		Prior to employing a candidate, the organization should ensure that: a. all personnel in the poliovirus facility should be subject to a formal selection process, including relevant background checks based on risk (e.g. employment references, security checks); b. appropriate controls are implemented should existing employees be transferred to areas where there may be an increased risk profile; c. all personnel entering areas with potential for exposure to poliovirus materials accept compliance with the health-care standards outlined in element 9 (Health Care), specifically including immunization with inactivated polio vaccine (IPV) every three years and an annual medical examination that includes the determination of poliovirus antibody titres; d. an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students), and measures are implemented to ensure they are applied where necessary.

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	5.2	**Training**		
CWA 4.4.2.4	5.2.1	Requirements and procedures for biorisk-related training of personnel are identified, established and maintained.		Procedures should: a. define biorisk training needs, including training specific to the characteristics of poliovirus and the procedures for minimizing risk within the facility, for all persons working within the containment perimeter as well as all those who may need to enter the perimeter, including medical support staff, maintenance staff and emergency responders; b. provide the required biorisk training; c. determine the effectiveness of the biorisk training; d. provide refresher biorisk training; e. restrict personnel from performing tasks for which they are not trained; f. maintain adequate records. Training should include raising awareness of biorisk issues among the personnel, including the relevance of human factors in biorisk management.
	5.3	**Competence**		
CWA 4.4.2	5.3.1	Personnel who have responsibilities and/or perform tasks within the poliovirus facility that may impact biorisk management in the workplace are competent to do so.		Competence is defined in relation to appropriate education, training and/or experience, together with a demonstrable ability to perform the task in a safe/secure manner. Procedures should: a. define competency needs; b. lead to the successful completion of the required training; c. lead to the ability to perform tasks under supervision and unsupervised; d. restrict personnel who have not demonstrated competence from performing tasks for which they are not eligible;

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				e. maintain adequate records. No worker should be exempt from demonstrating competence, irrespective of rank, experience or background.
CWA 4.4.2	5.3.2	Competence levels are judged on appropriate: 1. education; 2. training; 3. experience.		
CWA 4.4.2	5.3.3	The organization has defined required levels of competency.		
CWA 4.4.2	5.3.4	Records are maintained that show staff members have attained and demonstrated those levels of competency.		
CWA 4.4.2	5.3.5	Personnel who conduct activities within the facility are under close supervision until they have demonstrated competency.		
	5.4	**Continuity and Succession Planning**		
CWA 4.4.2.3	5.4.1	Adequate backup and contingency measures are in place to address the need for continuity and succession planning.		The organization should identify roles and individuals that require a substitute, ensuring the integrity of the facility is not compromised through short- or long-term absence. Such measures should include succession planning for personnel (technical, management and scientific, including contractors) to guarantee that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of that individual's departure or unavailability.
	5.5	**Exclusion**		
CWA 4.4.4.7.3	5.5.1	Measures are put in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility, where deemed necessary through risk assessment.		The measures should: a. remove access to the facility (e.g. taking away passes, changing locks and keys and access codes, and other security devices);

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				b. withdraw access to information related to the facility, including documentation, computerized records and data; c. allow the immediate physical removal of personnel if deemed necessary.
		Element 6 – Good Microbiological Technique The Good Microbiological Technique element examines how an organization identifies appropriate microbiological techniques and controls, and how they are implemented and reviewed. A major part of this element is the development of a biosafety or operations manual, which identifies hazards that may be encountered and specifies practices and procedures designed to minimize or eliminate risks. **Subelement** 6.1 Good Microbiological Technique		
	6	**GOOD MICROBIOLOGICAL TECHNIQUE**		
	6.1	**Good Microbiological Technique**		
CWA 4.4.4.5.1	6.1.1	All personnel handling poliovirus materials are competent in good microbiological techniques.		
CWA 4.4.4.5.1	6.1.2	Appropriate resources (including time and equipment) are available to ensure good microbiological techniques are adhered to effectively.		As appropriate, procedures should address risks associated with but not limited to the following: a. the handling of infectious poliovirus materials; b. animal handling; c. centrifugation; d. the control of needles and sharps; e. the correct use of vacuum pumps; f. culture, purification and storage techniques; g. the minimization/containment of aerosols; h. pipetting; i. sonication and other mechanical forms of cell/tissue disruption;

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				j. the use of biological safety cabinets (BSCs); k. the use of disinfectants, including spill control, routine decontamination, hand washing and showering. This list is not exhaustive and identifies only some activities that may be employed during typical laboratory work. These activities should be undertaken in association with appropriate procedures and working practices to ensure the control measures are effective under all foreseeable and credible operating scenarios. Appropriate control measures should be identified during risk assessments and designed to minimize poliovirus exposure, including: a. the required use of devices, e.g. BSCs, which are validated to maintain primary containment for all procedures using live poliovirus; b. the substitution of wild polioviruses with Sabin or further attenuated strains (as these become available) when live virus use is required.
		Element 7 – Clothing and Personal Protective Equipment (PPE) The Clothing and PPE element examines how an organization ensures that staff is provided with the right tools to minimize potential exposures, and that they know how and when to use them. This element specifically addresses the characteristics of some key items, for example the use of respirators and positive pressure suits, but also considers other commonly used items, including gloves, laboratory coats and footwear. **Subelement** 7.1 Clothing and Personal Protective Equipment (PPE)		
	7	**CLOTHING AND PERSONAL PROTECTIVE EQUIPMENT (PPE)**		

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	7.1	**Clothing and Personal Protective Equipment (PPE)**		
CWA 4.4.4.5.4	7.1.1	PPE needs are identified.		Measures in place should include: a. ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback); b. ensuring all personnel who must use PPE, including scientific staff, visitors and contractors, are identified and supplied with correctly fitting equipment and clothing; c. explicitly addressing the selection and use of PPE in SOPs, training and competency assessments; d. defining and conducting an appropriate programme to ensure routine checks and the maintenance of PPE are defined and carried out; e. defining and addressing the need for and provision of replacement and spare PPE; f. identifying and controlling the hazards associated with PPE itself (e.g. impaired dexterity or visibility); g. providing adequate PPE for use during both normal and emergency working conditions; h. ensuring procedures are in place for the cleaning and, if appropriate, the validated decontamination of used PPE, including safe storage prior to decontamination. PPE should be used in conjunction with, but never as a substitute for, reasonable and appropriate administrative and engineering controls. PPE should be used in accordance with established standards and manufacturer specifications. Employers should make PPE available to employees at no cost.
CWA 4.4.4.5.4	7.1.2	Suitable equipment is specified, made available, used and maintained appropriately within the facility.		Poliovirus-specific PPE needs should be determined by a risk assessment and may include the use of face shields, goggles,

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				gloves, masks, HEPA-filtered respirators and clothing strictly dedicated for use within the containment perimeter, including solid front gowns or other clothing protecting the body from exposure.
		Element 8 – Human Factors The Human Factors element is critical in any biorisk management programme, addressing issues as diverse as raising awareness of biorisk issues to initiating change management, and measuring and improving an organization's biorisk culture. Creating an environment where people are confident in reporting what has gone wrong and eliminating a "blame culture" are also addressed. **Subelement** 8.1 Human Factors		
	8	**HUMAN FACTORS**		
	8.1	**Human Factors**		
CWA 4.4.4.7	8.1.1	The organization has established and maintains a programme to address risk associated with human behaviour, including the management of how workers interact with the facility and its equipment.		The organization should ensure that factors associated with behaviours, and the need for individual support and communication, are managed responsibly, both to protect workers from direct hazards and to ensure they can function optimally within the facility. Many laboratory incidents are caused by inappropriate behaviour or human frailties, and a preventive and proactive approach to managing risk associated with the individual should be pursued, including the specific inclusion of such issues in risk assessments. The use of competent experts in assessing this area should be considered. Measures should be put in place to address: a. human reliability and behavioural safety, including adherence to procedures;

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				b. team building and motivation; c. communication, consultation and feedback; d. conflict management and resolution; e. the management of stress and fatigue; f. empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified; g. access to counselling; h. the avoidance of a "blame culture", including willingness to report accidents, incidents or unsafe conditions/behaviours, and protection of workers who do so; i. ergonomics, including equipment and work practice design to take account of individual needs; j. respect for individual privacy and dignity.
		Element 9 – Health Care The Health Care element evaluates the systems in place to protect workers from injuries and illnesses resulting from exposures to biological agents or their products, and how they are supported in the event of an accident. Subject areas covered include exposure control, health care and monitoring, immunization and the availability of competent first aid and external assistance. **Subelements** 9.1 Worker Health Programme 9.2 Vaccination of Personnel 9.3 Medical Emergencies		
	9	**HEALTH CARE**		
	9.1	**Worker Health Programme**		
CWA 4.4.4.6	9.1.1	The organization ensures that the risk to worker health, and that of other personnel whose health could be directly impacted by exposure to		The programme should address the needs of all individuals associated with the facility, including providing assurance that

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		poliovirus materials, is managed effectively, including through preventive and protective measures.		contractors and visitors receive the required level of protection in line with the activities they perform, as well as safeguarding workers' families.
CWA 4.4.4.6	9.1.2	The requirements of the health surveillance programme are determined by a defined health hazard identification and risk assessment process that involves all relevant personnel.		The programme may consult relevant personnel, including: a. the biorisk management adviser; b. the occupational health professional; c. facility personnel and employee representatives; d. external experts, including emergency responders; e. biorisk management committee members; f. veterinary and animal-care facility staff; g. human resource representatives; h. the communicable disease specialist; i. scientific management. Personnel considered to have significant risk of exposure should be identified and their health-care needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation/testing in the event of exposure. The individual's health and immune status, including an assessment of polio antibody titres as described under subelement 9.2.3, should be considered, and periodic checks appropriate to work conditions should be established. Although the primary focus of the assessment is exposure to the poliovirus materials being handled, other conditions that could impact personnel associated with the facility should also be addressed. These may include medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility/dexterity), the ability to safely use appropriate PPE, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status, substance abuse).

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				Information covered by the worker health programme should be treated confidentially. All individuals should have access to health-care consultation with either a corporate or institutional occupational health facility or an independent health-care provider, and be informed of the nature of any treatments/ vaccinations they may receive and their inherent risks and benefits.
	9.2	**Vaccination of Personnel**		
CWA 4.4.4.6.1	9.2.1	Based on risk, the need for vaccination has been determined and covers groups identified as being potentially exposed to poliovirus.		Measures should be implemented when needed to identify non-responders to vaccination (depending on the vaccine's response rate) and a policy should be in place to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas with risk of exposure. Areas requiring vaccinations to enter should be posted. Visitors, contractors and other non-core personnel should provide evidence of vaccination or of established immunity in accordance with the above requirement. Based on risk, reasonable measures should be taken to ensure that the vaccinations have been given and current certificates are valid. This may include examining original certificates and cross-checking with medical practices responsible for administering the vaccine. The organization should ensure the required or recommended vaccines are made available to concerned personnel. Vaccination should be seen as a risk-mitigation strategy, and its use should in no way infer that other controls, such as the use of good microbiological techniques or PPE, can be relaxed.
CWA 4.4.4.6.1	9.2.2	A vaccination policy has been defined and implemented.		

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CWA 4.4.4.6.1	9.2.3	Access to laboratories or work is controlled for individuals until they comply with the vaccination policy.		The organization will ensure the availability of IPV for individuals associated with the facility, consistent with the objectives to: a. restrict access to the containment facility to individuals who have demonstrable immunity to poliovirus (defined as annual verification of serum neutralizing antibody titres of 1:8 or greater against all three poliovirus types), including: – personnel assigned to work within the containment perimeter; – contractors, auditors and visitors who must enter the containment perimeter; – support personnel and contractors working immediately outside the containment perimeter (e.g. maintenance personnel, cleaning staff); b. administer an IPV booster every three years to all personnel mentioned above or in the event of an antibody titre determined to be <1:8 via annual testing; c. provide effective secondary population safeguards by an established programme of education and promotion to encourage acceptance of immunization by: – non-core facility personnel, including contractors; – workers' families/companions; – other groups in contact with the facility.
	9.3	**Medical Emergencies**		
CWA 4.4.5.2	9.3.1	A system is established to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers.		Procedures should ensure that adequate emergency planning is provided to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, to members of the broader community and to environmental conditions that may have been affected by the incident. It should include identifying emergency scenarios (e.g. involving an infected worker/family member)

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				and necessary support measures (e.g. liaison with emergency services/local authorities), and providing equipment and other resources required to manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained. Procedures should ensure that adequate first aid is available in relation to credible accident scenarios, as identified during risk assessments. The procedures should address the need for adequately trained personnel and their availability, as well as equipment and other materials that may be required to provide treatment. Procedures should ensure additional competent medical support is identified and made available (e.g. hospitals, isolation units).
		Element 10 – Emergency Response and Contingency Planning The Emergency Response and Contingency Planning element examines the structures and mechanisms in place to cope with working outside normal operating conditions, and how to react proportionally to emergency situations. Issues addressed include physical requirements, capacity in terms of personnel and facilities and of protective and rescue systems, emergency communications, decision-making authorities and the development and testing of emergency scenarios and simulations. **Subelements** 10.1 Emergency Scenarios 10.2 Emergency Response and Planning 10.3 Emergency Plans		

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		10.4 Emergency Exercises and Simulations 10.5 Contingency Plans		
	10	**EMERGENCY RESPONSE AND CONTINGENCY PLANNING**		
	10.1	**Emergency Scenarios**		
CWA 4.4.5.1	10.1.1	All credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.		To plan for emergencies, all credible emergency scenarios must be considered. It is unlikely that all potential scenarios will be credible, but all reasonable threats should be considered and recorded and, where appropriate, the rationale for dismissing any issue should be provided. Scenarios considered should include: a. an infected/potentially infected worker or other contact (e.g. family member, emergency responder or community member); b. accident or illness to a worker within the containment area and need for evacuation; c. fire; d. flood; e. breach of security; f. explosion; g. the potential loss of poliovirus through theft or any other reason; h. unexpected virulence (unknown biological agents or biological agents expected to be avirulent); i. physical facility and equipment failure, including a control system failure of the disinfection regime; j. utility failure including electricity, gas, steam and water supplies; k. a major spillage/aerosol release;

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				l. environmental release; m. a natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics); n. an act of terrorism or deliberate vandalism, extortion; o. intense media attention.
	10.2	**Emergency Response and Planning**		
CWA 4.4.5	10.2.1	Plans and procedures are established and maintained to: 1. identify the potential for incidents and emergency situations involving biological agents, toxins and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them.		
CWA 4.4.5	10.2.2	Emergency planning covers all aspects of biorisk and includes general safety, security and medical issues. A system is established to effectively manage a confirmed facility-associated poliovirus infection until the individual is free of poliovirus in stools for three consecutive days. This includes procedures for: 1. isolating infected individuals, particularly from children and the unimmunized; 2. collecting and disinfecting stool and associated waste; 3. educating families and frequent contacts on the risk posed by poliovirus infection and the procedures for isolation; 4. communicating with relevant national and local officials to evaluate the needs to implement community immunization response plans; 5. notifying WHO; 6. disinfecting areas potentially contaminated by infected individuals.		
	10.3	**Emergency Plans**		

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CWA 4.4.5.2	10.3.1	Biorisks are taken into account when preparing and implementing emergency plans. A system is established to effectively manage incidents that are determined by the evaluation/response team to be significant poliovirus exposures, including: 1. implementing full preventive measures by isolating individuals under evaluation from children and the unimmunized in particular, and securing stool and associated waste; 2. educating individuals under investigation, their family and close contacts on the risk of poliovirus infection to the community, the procedures for diagnosis and the precautionary measures required to prevent possible transmission; 3. initiating procedures to determine whether individuals are infected, by collecting and testing nose, throat and stool specimens daily for a minimum of seven days post-exposure.		The organization should ensure that plans address the following needs at a minimum: a. identifying those responsible for devising, implementing and testing the control measures specified, along with ensuring their conclusions are effectively communicated to all relevant personnel; b. ensuring the legality and enforceability of proposed emergency response plans; c. responding during emergencies occurring outside working hours as well as those occurring during normal working hours; d. providing for periods of reduced staff availability (e.g. during weekends and holiday periods); e. ensuring emergency access/exit, including the ability to override access controls as appropriate; f. providing emergency exit routes that avoid evacuating people through containment areas; g. providing for the safe removal, transport, transfer, treatment and accommodation of contaminated persons and objects; h. informing visitors and contractors about emergency response plans and the possible consequences of exposure.
CWA 4.4.5.2	10.3.2	Control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency.		
CWA 4.4.5.2	10.3.3	Emergency plans are effectively communicated to all employees and relevant third parties, and tested with the goal of making everyone aware of their obligations.		In the event of an emergency situation, it may be necessary to involve parties external to the organization. Based on the credible scenarios identified, the organization should pinpoint such agencies to establish their role in responding to a given situation. The organization may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties on their role and any risk exposures they may face, and ensure their actions will not unnecessarily increase the risk associated with

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				the emergency (e.g. uncontrolled use of water for fires). Contact information should be documented and made available to personnel responsible for coordinating the emergency response activity. External agencies consulted may include: a. police and security services; b. fire services; c. ambulance and local hospitals/health-care providers; d. transport providers/couriers; e. local and national government officials; f. environmental authorities; g. WHO.
	10.4	**Emergency Exercises and Simulations**		
CWA 4.4.5.3	10.4.1	Structured and realistic emergency exercises and simulations, including security drills, are conducted at regular intervals based on risk, to test the plans, prepare personnel and learn from any good practices or deficiencies identified.		Exercises and simulations should be conducted to provide assurance that plans are effective and to learn from any lessons that arise. Exercises should be planned and every effort made to ensure they realistically represent the events simulated. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of an exercise should be documented and reviewed for lessons learnt, and feedback on performance should be provided to the appropriate personnel. Any resulting actions should be recorded and allocated to named individuals, and measures should be put in place to ensure they are closed out effectively.
	10.5	**Contingency Plans**		

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CWA 4.4.5.4	10.5.1	In the event of an emergency, adequate contingency measures are in place to ensure the safety and security of continued operations.		Normal operating conditions may be disrupted in the event of an emergency or unforeseen event. This could range from safely shutting down work during a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively, and contingency plans put in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems (e.g. power supplies), alternative means of decontaminating materials in the event of the failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shutdown of operations in extreme situations.
		Element 11 – Accident/Incident Investigation The Accident/Incident Investigation element addresses activities that define the facts and circumstances related to an event, determine the causes and develop remedial action to control biorisk and prevent recurrence. Often, chance is the only reason a property-damage accident or near-miss incident does not result in infection or personal harm. Likewise, chance alone often determines whether an accident's consequences are minor, serious or catastrophic. This element examines the organization's reporting and investigation system, whether the right people are involved and how corrective and preventive actions are implemented. **Subelement** 11.1 Accident/Incident Investigation		
	11	**ACCIDENT/INCIDENT INVESTIGATION**		
	11.1	**Accident/Incident Investigation**		

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CWA 4.5.4.1	11.1.1	Documented procedures are established and maintained to define record, analyse and learn from accidents and incidents involving poliovirus materials.		Procedures should be put in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel. It may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed; it is essential that lessons be learnt and improvements made where possible. The accident/incident investigation process should include at a minimum: a. creating a culture of self-reporting incidents, including "near misses" and incidents that may trigger an investigation or emergency response; b. identifying those responsible for maintaining the accident/ incident reporting system; c. defining what constitutes an accident/incident and what triggers recording and reporting, with emphasis on events that may result in exposure to live poliovirus (e.g. sticks, spills, splashes, sprays, leaks, aerosol generating events); d. defining what constitutes a significant poliovirus exposure (e.g. ingestion) and thresholds for initiating procedures to determine whether individuals are infected; e. specifying required documentation to support the system, as well as the frequency and distribution of reports generated and communicated to relevant personnel; f. identifying the reports that will be generated, as well as their frequency and distribution; g. establishing a poliovirus incident evaluation/response team (composed of facility medical, public-health and polio-specific expertise) that determines whether an exposure is significant, reports its findings to the senior manager and recommends such actions as deemed necessary;

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				h. establishing and publicizing 24-hour accident/incident reporting channels, and identifying those responsible for maintaining the system; i. ensuring an analysis of trends; j. identifying root causes using individuals trained in investigation techniques; k. providing feedback at regular intervals and action-tracking mechanisms to ensure lessons learnt result in action to avoid repeating such events and/or to minimize their potential impact; l. identifying where security professionals may be required to coordinate with law enforcement.
		Element 12 – Facility Physical Requirements The Facility Physical Requirements element looks at how the organization addresses biorisk during periods when something new is introduced or the existing set-up is changed. Issues addressed include identifying the people who need to be involved and consulted, incorporating biorisk into planning, approaching commissioning in a structured way (including the role of suppliers), considering the physical characteristics of the materials used and carrying out any certification that may be needed. **Subelements** 12.1 Planning, Design and Verification 12.2 Commissioning and Decommissioning 12.3 Infrastructure and Operational Management		
	12	**FACILITY PHYSICAL REQUIREMENTS**		
	12.1	**Planning, Design and Verification**		
CWA 4.4.4.8.1	12.1.1	A formal planning, design and redesign process is adopted for the facility, based on an assessment of risk associated with the materials to be used and activities undertaken.		A formal design process means a structured and documented approach, whereby the facility's needs are determined through risk assessment. Engineering and operational solutions will

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				be incorporated that are consistent with the risk posed by the properties of the materials to be stored and handled in the facility and the nature of the work to be carried out.
CWA 4.4.4.8.1	12.1.2	The design process identifies and incorporates all relevant legislative requirements, together with information from recognized standards, guidelines (WHO *Laboratory biosafety manual, Third edition*, 2004), industry good practices and facility-specific risk assessments.		The design process should include identifying and reviewing relevant legislation and codes of practice (including building codes as well as those related to laboratory biosafety/laboratory biosecurity) and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and standards of acceptance to ensure performance. The process should be documented and transparent to provide assurance that it has been comprehensive and thorough.
CWA 4.4.4.8.1	12.1.3	The design process identifies and facilitates consultation with all relevant parties associated with the facility and its operation.		The design process should include identifying and consulting with individuals involved in the planning, construction, operation and maintenance of the facility. The following roles/individuals should be considered in terms of information requirements and consultation: a. scientific personnel and other end users; b. the biorisk management adviser and biorisk management committee; c. biosecurity and/or security personnel; d. designers (architects and engineers); e. constructors; f. maintenance engineers; g. material and equipment suppliers; h. commissioning agents; i. certifiers; j. regulators; k. WHO;

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				l. first responders; m. other relevant parties identified in risk assessments. If justified, and based on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specifications: a. are in line with accepted good practice; b. incorporate features capable of providing assurance regarding the control of poliovirus materials; c. integrate relevant legislative requirements, as well as standards and risk assessment findings, in the design.
CWA 4.4.4.8.1	12.1.4	All design features, construction techniques, materials and equipment selected are documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specifications.		
CWA 4.4.4.8.1	12.1.5	New construction and physical facility modifications are carried out according to an approved plan.		
	12.2	**Commissioning and Decommissioning**		
CWA 4.4.4.8.2	12.2.1	A formal process exists for: 1. the initial commissioning of new facilities; 2. the final decommissioning of existing facilities.		Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase during the first stage of science programme definition to ensure the expectations for the building are achievable. The commissioning plan should be developed in detail in parallel with the physical concept to ensure the expectations for the building are measurable. The commissioning plan should clearly identify all the steps from beginning to end, providing examples and including the conditions of acceptance of each step as a prerequisite for proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after any temporary

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				shutdown. The commissioning process should provide the benchmark for acceptable facility operation and the description of the programme to be put in place to maintain that level of performance. The decommissioning process should identify the decontamination procedures and security-related measures that must be in place for the facility's temporary or final shutdown. The decommissioning programme should describe not only the procedures, but also the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned facility can be re-entered.
	12.3	**Infrastructure and Operational Management**		
CWA 4.4.4.8	12.3.1	Facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management. The poliovirus facility incorporates features that are guided by assessments of the risk of poliovirus reintroduction in the community and includes the following provisions: a. Poliovirus facilities are located in countries with demonstrated high	Facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management. The poliovirus facility incorporates features that are guided by assessments of the risk of poliovirus reintroduction in the community and includes the following provisions: a. Poliovirus facilities are located in countries with demonstrated high	

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		national immunization coverage (= DTP3 coverage). b. Poliovirus facilities are located in areas with closed sewage systems with secondary or greater treatment of effluents. c. Poliovirus facilities are either poliovirus dedicated or used on a campaign basis with documented effective decontamination procedures between periods of work with agents other than poliovirus. d. The containment perimeter is a defined working area sealable for gaseous decontamination and with sealed penetrations to prevent uncontrolled outward airflow. The containment perimeter is required irrespective of the choice of primary containment. e. The use of devices (e.g. BSCs) that are validated to maintain primary containment is required for all procedures using live poliovirus. Facilities using Class III BSCs will meet all physical aspects of this standard with deviation	national immunization coverage (>90%). b. Poliovirus facilities are located in areas with demonstrated low poliovirus reproductive rates (R_0), i.e. in areas with closed sewage systems with secondary or greater treatment of effluents. c. Poliovirus facilities are either poliovirus dedicated or used on a campaign basis with documented effective decontamination procedures between periods of work with agents other than poliovirus. d. The containment perimeter is a defined working area sealable for gaseous decontamination and with sealed penetrations to prevent uncontrolled outward airflow. The containment perimeter is required irrespective of the choice of primary containment. e. The use of devices (e.g. BSCs) that are validated to maintain primary containment is required for all procedures using live poliovirus. Facilities using Class III BSCs will meet all physical aspects of this standard with deviation	

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		in procedures permitted during the BSC's normal operation (i.e. showering out is not required when Class III BSC is functioning properly). f. Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time, alarms, and associated operating procedures to ensure the building systems function effectively at all times. g. Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing fully functional Class III BSCs or similar isolators (in such facilities, showering out is required in the event of an uncontrolled breach of the primary containment equipment). h. Throughout the poliovirus type 2 containment period, a dose of IPV will be introduced, high global vaccine coverage will be	in procedures permitted during the BSC's normal operation (i.e. showering out is not required when Class III BSC is functioning properly). f. Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time, alarms, and associated operating procedures to ensure the building systems function effectively at all times. g. Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing fully functional Class III BSCs or similar isolators (in such facilities, showering out is required in the event of an uncontrolled breach of the primary containment equipment). h. The controlled air system maintains directional airflow via a dedicated ventilation system with ductwork sealable for gaseous	

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		maintained (population immunity is not expected to decline) and the use of monovalent oral polio vaccine type 2 (mOPV2) for outbreak response is considered. Where evidence of the satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, the controlled air system maintaining directional airflow will not require HEPA filtration on exhaust.	decontamination, HEPA filtration on exhaust, backflow protection on supply, and monitors/alarms to ensure directional airflow can be readily validated.	
		i. Throughout the poliovirus type 2 containment period, a dose of IPV will be introduced, high global vaccine coverage will be maintained (population immunity is not expected to decline) and the use of mOPV2 for outbreak response is considered. Where evidence of the satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, decontamination of effluents is not required.	i. The decontamination of all effluent (including shower water, eyewash, unsterilized autoclave condensate) from within the containment perimeter is achieved through a validated inactivation procedure. Backflow prevention is implemented on all services/ utilities entering the facility (water, gases) and via measures to prevent release through traps, sinks and shower drains.	
		j. The decontamination of all materials exiting the facility is achieved through a validated sterilization/decontamination procedure. Examples include:	j. The decontamination of all materials exiting the facility is achieved through a validated sterilization/decontamination procedure. Examples include:	

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		– a dedicated pass-through autoclave with a bioseal, interlocking doors to prevent opening the clean side prior to cycle completion, HEPA filtration of air discharge, cycle recording mechanisms and alarms; – a material airlock/ decontamination chamber sealable for gaseous decontamination; – a dunk tank containing sufficient active compound to inactivate poliovirus. The poliovirus animal facility will incorporate features guided by risk assessments as described above and will meet all poliovirus containment criteria as described in this document, including: a. complying with containment criteria for animal facilities, consistent with the controls outlined in other sections of this document; b. specially training and supervising personnel responsible for inoculating, harvesting, sampling, performing animal autopsies, and for any other manipulations with poliovirus infected animals;	– a dedicated pass-through autoclave with a bioseal, interlocking doors to prevent opening the clean side prior to cycle completion, HEPA filtration of air discharge, cycle recording mechanisms and alarms; – a material airlock/ decontamination chamber sealable for gaseous decontamination; – a dunk tank containing sufficient active compound to inactivate poliovirus. The poliovirus animal facility will incorporate features guided by risk assessments as described above and will meet all poliovirus containment criteria as described in this document, including: a. complying with containment criteria for animal facilities, consistent with the controls outlined in other sections of this document; b. specially training and supervising personnel responsible for inoculating, harvesting, sampling, performing animal autopsies, and for any other manipulations with poliovirus infected animals;	

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		c. requiring the use of devices (e.g. BSCs) that are validated to maintain primary containment for all animal manipulations with live poliovirus; d. housing infected animals separately; e. maintaining barriers to prevent infected animals from escaping; f. maintaining accurate records and accounting for all infected animals; g. meeting international criteria for laboratory animal care; h. using security procedures specific for facilities housing animals involved in biomedical research.	c. requiring the use of devices (e.g. BSCs) that are validated to maintain primary containment for all animal manipulations with live poliovirus; d. housing infected animals separately; e. maintaining barriers to prevent infected animals from escaping; f. maintaining accurate records and accounting for all infected animals; g. meeting international criteria for laboratory animal care; h. using security procedures specific for facilities housing animals involved in biomedical research.	
		Element 13 – Equipment and Maintenance The Equipment and Maintenance element aims to ensure that biorisk is taken into consideration during the selection of all equipment that has implications for its control. Emphasis is placed on selection procedures, the maintenance of asset registers, control over where the equipment may be moved, and what it will be used for over its working life. Particular attention is also given to ensuring the equipment functions properly by following prescribed periodic and predictive maintenance, supported by adequate breakdown response. **Subelements** 13.1 Maintenance Management		

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		13.2 Control of Equipment 13.3 Calibration 13.4 Certification 13.5 Validation		
	13	**EQUIPMENT AND MAINTENANCE**		
	13.1	**Maintenance Management**		
CWA 4.4.4.8.3	13.1.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are maintained in a manner consistent with the intent and requirements of the biorisk management programme.		The maintenance programme should apply to all aspects of the physical structure (including finishes and seals, where appropriate) and equipment therein. All materials used should be specified to ensure they can perform in line with predetermined criteria. An appropriate maintenance plan will be addressed as part of that specification process. In planning and conducting maintenance activities, the organization should consider: a. adequately maintaining the facility's physical integrity and its fixtures and fittings; b. ensuring competent individuals perform the maintenance activities, and the risks associated with the work have been subjected to a risk assessment; c. ensuring adequate controls are in place to prevent workers from being exposed to poliovirus during their work; d. identifying and recording maintenance requirements during the construction of facilities or when equipment is purchased/ acquired; e. creating and maintaining a maintenance register for all applicable equipment; f. identifying and conducting planned maintenance activities at an appropriate frequency; g. ensuring unplanned (breakdown) maintenance is adequately provided for so the facility's integrity is maintained at all times;

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				h. determining and monitoring predictive maintenance requirements and associated indicators and monitors; i. ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement; j. establishing a pest control programme.
	13.2	**Control of Equipment**		
CWA 4.4.4.8.3	13.2.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are controlled in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting equipment controls, the organization should consider: a. identifying equipment in line with work needs, which can be demonstrated as fit for purpose;. b. controlling the purchase/acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel; c. controlling the entry and exit of equipment to and from the poliovirus facility, including decontamination requirements (e.g. air locks and decontamination); d. ensuring the asset register is regularly updated; e. ensuring stocks and supplies of equipment are sufficient
	13.3	**Calibration**		
CWA 4.4.4.8.3	13.3.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are calibrated in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting calibration activities, the organization should consider: a. identifying and recording calibration requirements at the time of purchase/acquisition; b. identifying the standards/tests to use to ensure the equipment is correctly calibrated; c. establishing procedures to conduct calibrations on equipment used in live virus areas; d. creating a documented and up-to-date calibration register for all applicable equipment;

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				e. ensuring calibration is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.4	**Certification**		
CWA 4.4.4.8.3	13.4.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are certified in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting certification activities, the organization should consider: a. identifying and recording certification requirements at the time of purchase/acquisition of equipment, including relevant and current standards against which to certify; b. ensuring competent and independent certifiers are used for the certification process; c. ensuring certification is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.5	**Validation**		
CWA 4.4.4.8.3	13.5.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are validated in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting validation activities, the organization should consider: a. identifying and recording validation requirements at the time of purchase/acquisition; b. identifying the standards/tests to use to ensure the equipment is correctly validated; c. creating a documented and up-to-date validation register for all applicable equipment; d. ensuring validation is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments; e. ensuring competent and independent validation mechanisms are used for the validation process. For physical security systems, the analogous concept is

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				performance testing and evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed.
		Element 14 – Decontamination, Disinfection and Sterilization The Decontamination, Disinfection and Sterilization element examines the controls in place to ensure that appropriate disinfection, decontamination and sterilization routines manage the risk presented by the organisms and work activities undertaken. The element addresses general requirements for procedures, training and waste disposal as well as more specific issues, including the potential need for specialist laundering and issues specific to animal facilities. **Subelements** 14.1 Management of Biological Waste 14.2 Inactivation of Poliovirus Materials		
	14	**DECONTAMINATION, DISINFECTION AND STERILIZATION**		
	14.1	**Management of Biological Waste**		
CWA 4.4.4.5.3	14.1.1	The organization has established and maintains an appropriate waste management policy for poliovirus materials. No viable poliovirus will be released from the facility unless approved by the competent authority for transfer to another approved facility under controlled conditions. Potential routes whereby viable poliovirus could unintentionally exit the facility will be identified and adequate prevention measures put in place.		The organization should have a validated procedure for the inactivation of poliovirus waste products. The following elements should be considered for a waste management policy: a. ensure a programme is in place to minimize waste production; b. ensure effective waste audit trails are in place and documented; c. provide adequate facilities and procedures for the storage of waste (including short-term storage); d. ensure methods are available to effectively segregate and decontaminate mixed waste (e.g. infected animals that have received radioactive materials); e. ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transport.

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CWA 4.4.4.5.2	14.1.2	All contaminated or potentially contaminated waste items (including those that may result from an emergency) have been: 1. identified; 2. documented.		Sources of contamination that should be considered include: a. personnel; b. clothing and PPE; c. glassware; d. equipment; e. cultures and associated materials; f. spill clean-up materials and equipment; g. possibly infectious microorganisms, toxins and contaminated materials; h. paper and plastic waste; i. needles, syringes and sharps; j. waste water, including that from sinks and showers; k. air; l. filters and air handling systems; m. discarded equipment used in the facility; n. animals exposed to laboratory poliovirus; o. animal carcasses and bedding; p. facilities. All potential waste streams and other sources of contamination should be identified and documented. For each of these sources, procedures should be put in place to validate the decontamination regime, and records will demonstrate that no contaminated persons/materials leave the facility and that inactivation measures have been implemented effectively.
CWA 4.4.4.5.2	14.1.3	Efficient procedures are in place to devise effective decontamination and other appropriate treatments.		Contaminated personnel may include core personnel working within the facility, contractors and emergency response

CWA15793 Clause No.[18]	Biorisk Management Element No.	Requirements for Containment of WPV2	Requirements for Final Containment of all WPV	Guidance
				personnel. Cultures and associated materials may be a source of contaminated supernatants, aspirates and culture media. Infected biological materials may also include infectious human, animal or plant specimens. In some instances, contaminated dedicated equipment, such as fire-fighter apparel or ambulance tools, may need to be held on-site if they cannot be effectively decontaminated. Risk assessment should be an integral part of the process to identify and develop effective decontamination regimes.
	14.2	**Inactivation of Poliovirus Materials**		
CWA 4.4.4.5.2	14.2.1	Procedures are established and maintained to ensure appropriate disinfection and decontamination methods are chosen and implemented effectively. Procedures are established, validated and maintained for the effective poliovirus decontamination of the facility. **Inactivation of poliovirus**. Procedures are established and maintained to ensure the complete inactivation of all poliovirus from all materials and solid waste streams leaving the containment perimeter, including: 1. Heat sterilization (autoclaving) is the preferred method to inactivate polioviruses. 2. SOPs are available to address both routine and non-routine activities (e.g. daily routines vs major spills). 3. SOPs are developed to respond to the failure of the decontamination procedure or equipment. 4. SOPs are validated and shown to be effective against poliovirus prior to their use. 5. All materials leaving the containment perimeter, including clothing and liquid/solid waste, are heat sterilized or subject to chemical treatment of		Whatever poliovirus materials are handled, a number of effective inactivation methods are likely to be available. The organization should ensure data are available to demonstrate that the methodology selected is capable of inactivating the poliovirus materials under the specific conditions encountered in the facility. Validation measures should consider such issues as: a. the nature of the material being treated (e.g. volume, presence of protein/other potentially inhibitory substances); b. contact times, material compatibility issues (e.g. interaction with stainless steel or rubber seals); c. potential health hazards associated with the disinfectant; d. the need to maintain the required level of active compound, including deterioration over time. In planning and conducting decontamination activities, the organization should consider: a. ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and such concentrations are maintained throughout the process, including conducting specific

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		proven effectiveness prior to their removal. 6. All materials leaving the containment perimeter are accompanied by documentation on their decontamination. 7. Resources are available to deal with emergencies, accidents and other incidents. 8. Any live poliovirus that may be removed from the facility will be taken away in a dunk tank, decontamination chamber or other validated mechanism to ensure the disinfection of the exterior surfaces of any packaging materials used. 9. The facility inactivates all waste and potentially contaminated material before it is passed to contractors or other third parties for waste disposal.		validation activities where necessary; b. providing adequate facilities and procedures for the storage of waste (including short-term storage); c. ensuring methods are available to effectively decontaminate mixed waste (e.g. infected animals that have received radioactive materials); d. ensuring methods are available, where appropriate, to decontaminate sensitive equipment not suitable for autoclaving (e.g. computers); e. implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and the use of indicators in autoclaves); f. decontaminating protective clothing by appropriate means prior to leaving the facility; g. ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during the handling and transport of materials inside and outside the facility; h. implementing programmes to ensure the amount of contaminated waste is minimized.
		Element 15 – Transport Procedures The Transport Procedures element explores how an organization deals with issues associated with the internal and external transport of biological materials, and looks at the necessary roles and responsibilities, materials and equipment, as well as the need to work with specialist couriers and shipping agents. **Subelement** 15.1 Transport Procedures		
	15	**TRANSPORT PROCEDURES**		

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	15.1	**Transport Procedures**		
CWA 4.4.4.9	15.1.1	Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials, both inside and outside the facility containment perimeter, are established and maintained in accordance with legal requirements for the transport of dangerous goods.		In planning and conducting transport activities, the organization should consider: a. ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines; b. ensuring the internal transport of poliovirus (within the facility, but outside the containment perimeter) meets the equivalent biosafety and biosecurity standards required for external transport outside the facility; c. ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transport process; d. selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely; e. determining whether a request for poliovirus materials is being made by an approved facility for a legitimate reason, and equivalent controls are applied to the importation of material to the facility; f. identifying the need for formal documented transfer forms signed by the responsible management representative authorizing the movement of the materials; g. using document controls that allow the traceability of material movements; h. identifying and implementing adequate and proportionate emergency response and contingency plans associated with the transport of poliovirus materials, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off.

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		Element 16 – Security The Security element examines how an organization manages security with regard to biorisk. The element looks not only at some of the more obvious issues, such as access control, but also at the need for information security and support from external agencies. **Subelements** 16.1 Physical Security 16.2 Information Security 16.3 Personnel Control 16.4 Personal Security 16.5 Contractors, Visitors and Suppliers		
	16	**SECURITY**		
	16.1	**Physical Security**		
CWA 4.4.4.8.4	16.1.1	Controls are implemented and maintained for the physical security of cultures, specimens, samples and potentially contaminated materials or waste, determined as part of the risk assessment process.		Measures should be put in place to minimize the potential for release or removal of poliovirus materials from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms. In planning and conducting security risk assessments, the organization should consider: a. the theft or diversion of poliovirus materials or related equipment, documents or data; b. sabotage, including vandalism and tampering; c. break-in and intrusion; d. labour issues and disputes; e. kidnapping and extortion; f. weather-related emergencies (e.g. earthquake, tsunami, flood, tornado, hurricane);

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				g. workplace violence; h. the failure of utilities; i. picketing, occupation and barricade; j. the screening and isolation of suspect packages; k. acts of terrorism; l. civil unrest or war; m. cyberthreats. Care should be taken to coordinate biosecurity and biosafety measures to manage and minimize conflicting priorities. Security breaches should be reported, recorded and investigated as accidents and incidents. Procedures for the physical security of poliovirus materials, including cultures, specimens, samples and potentially contaminated materials, should be implemented and maintained, ensuring: a. the containment facility is located on a secure site with perimeter control to discourage unauthorized access; b. the containment facility is located away from uncontrolled traffic flows and its entrance is via a locked door with two-factor access control measures (e.g. requiring an electronic pass and personal access code); c. a second person within the containment perimeter or in close proximity is aware during poliovirus manipulations of the work being conducted and is available for contact if needed; d. the facility's perimeter is subject to constant monitoring (e.g. through the use of alarms, security personnel and closed-circuit television);

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				e. measures are implemented to identify and record all personnel in the facility at any point in time; f. anti-intrusion alarms and sensors are installed, including interfaces with police and other security services; g. panic buttons and "silent" emergency alert measures are implemented (e.g. key codes to alert security in the event of a hostage situation).
	16.2	**Information Security**		
CWA 4.4.4.8.5	16.2.1	A policy and procedure are in place to identify sensitive information.		The information generated by a laboratory can be as valuable and/or dangerous as the poliovirus materials stored at the facility. Adequate measures to prevent the unauthorized release of such information are critical. Procedures addressing information security should consider: a. the secure storage of all sensitive written records and data (e.g. virus inventories, security plans, security inspection reports, design drawings, maintenance plans, human resource information including worker contact details), including electronic records and electronic signatures; b. computer security, including robust Internet firewalls and encryption protocols; c. strict policies regarding PCs, laptop computers, storage media and cameras, among others, entering or leaving the facility; d. the thorough destruction of paper files to be discarded, and complete erasure of unwanted electronic files.
CWA 4.4.4.8.5	16.2.2	A review and approval process is used to control access to sensitive information.		
	16.3	**Personnel Control**		

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CWA 4.4.4.7.1	16.3.1	A personnel reliability policy is defined and implemented.		The nature and extent of the measures required for the personnel reliability assessment should be determined as part of the risk assessment process. The organization will ensure that access to poliovirus containment areas is limited to members of personnel who have been screened for subversive behaviours/ associations or criminal records or to those accompanied at all times by authorized individuals (as in the case of visitors, contractors, etc.). The screening includes: a. association with organizations that could present a threat to the facility's integrity; b. medical conditions that could lead to unstable/undesirable behaviour; c. assurance that individuals do not work under the influence of drugs or alcohol.
CWA 4.4.4.7.1	16.3.2	The organization ensures that individuals' access to facilities or work is controlled, according to the policy.		Where lawful and appropriate as determined by risk assessments, screening may include such checks as identity and immigration status, membership in organizations hostile to biological research, criminal records and financial probity.
	16.4	**Personal Security**		
CWA 4.4.4.10	16.4.1	A policy is in place to provide personal security support services to staff members, including, where appropriate, personal security awareness training. Documented security drills and exercises are conducted and prepare personnel and learn from any deficiencies.		Personal security is concerned with staff security during off-duty hours while away from the facility. During these times, staff members are vulnerable because of their function or position.
	16.5	**Contractors, Visitors and Suppliers**		
CWA 4.4.4.7.2	16.5.1	The organization ensures that suppliers, contractors, visitors and subcontractors adhere to the established management systems' requirements and do not compromise the facility's biorisk management.		

ANNEX 3

Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no WPV)

Introduction

A facility-associated poliovirus infection or release into the environment during the Endgame Strategy period and following eradication and cessation of oral polio vaccine (OPV) use will be a public health event of international proportions. The *Global Action Plan* addresses that risk by establishing a post-eradication/post-OPV cessation goal of retaining poliovirus in a limited number of poliovirus-essential facilities worldwide. The *Global Action Plan* further reduces the risk posed by these facilities by establishing international standards for primary safeguards of facility containment, secondary safeguards of population immunity, and tertiary safeguards of facility location and assurance through national and international oversight that such standards are met.

Primary safeguards minimize the risk of facility-associated poliovirus release and include facility management; the design and operation of the containment facility; practices and procedures; the vaccination of facility personnel and their close family members; and contingency plans for potential virus release or exposure. Secondary safeguards of population immunity minimize the consequence of a poliovirus release from a poliovirus-essential containment facility and consist of a national routine childhood immunization policy and demonstrated high (=DTP3; >90%) national population coverage (12). Tertiary safeguards of facility location minimize the risk of transmissible poliovirus by placing such facilities in areas with closed sewage systems with secondary or greater effluent treatment. Primary and secondary safeguards are required within three months of the tOPV-bOPV switch for poliovirus-essential facilities handling and storing only OPV2/Sabin2 materials, and three months after bOPV cessation for poliovirus-essential facilities handling and storing any OPV/Sabin materials.

This "Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials" describes the international requirements for the primary safeguards established for poliovirus-essential laboratories handling and storing OPV/Sabin materials or for Sabin-IPV production facilities. This standard is based on CWA15793, *Laboratory biorisk management* (2), the principles of the WHO *Laboratory biosafety manual,* Third edition (17) and the extensive poliovirus scientific literature spanning nearly seven decades (10). This standard serves as the framework for national certification and WHO verification (Annex 4). It consists of 16 elements and subelements based on the principles of a quality management system. It assumes that the organization is best placed to understand the risks associated with its work and can manage those risks in a number of ways acceptable to the national and international bodies responsible for facility oversight. This standard further assumes that poliovirus-essential facility personnel and management at all levels fully appreciate the enormity of the consequences of accidental or malicious poliovirus release in the post-eradication/post-OPV era and are prepared to demonstrate that the appropriate systems and controls are in place to manage those risks.

Poliovirus facility-associated risks

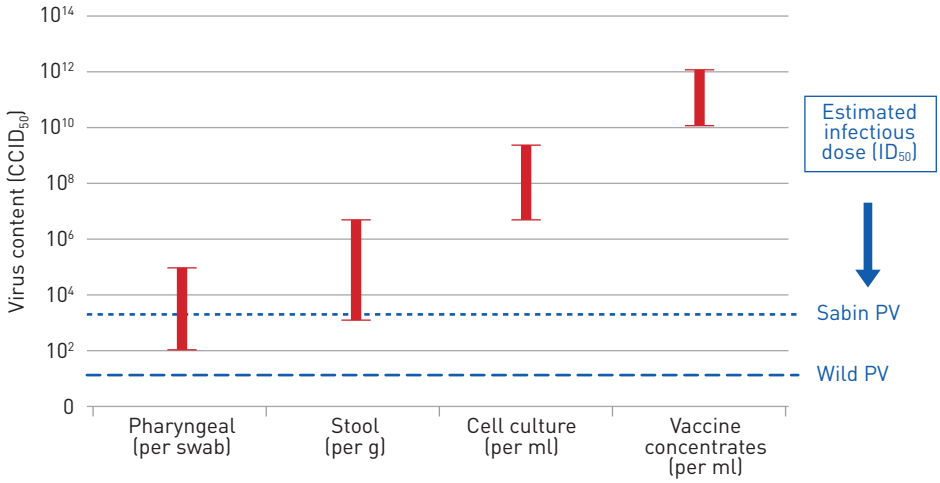
Polioviruses under moist conditions in clinical or environmental samples can survive indefinitely in the laboratory freezer (<-20 °C), for many months in the refrigerator and for weeks on the bench top at ambient temperatures (18). Infectivity is inactivated by dehydration, heat (>50 °C) or treatment with dilute solutions of formaldehyde or bleach at appropriate concentrations.

The most common routes of exposure to infectious agents in the facility environment are (1) ingestion; (2) inhalation; (3) injection; and (4) contaminated skin and mucous membranes. The infectious dose is a factor of virus virulence, the route of presentation and virus particles in sufficient number to overcome mechanical loss and natural and immune host defences. In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/g (Sabin) to $10^{4.3}$ $CCID_{50}$/g (wild) in stool samples, to10^{8} $CCID_{50}$/ml in cell culture harvests, and 10^{11} $CCID_{50}$/ml in concentrates in vaccine production facilities. Sabin strains are less pathogenic than wild and have lower secondary infection rates, but all three Sabin virus types have been linked to vaccine-derived poliovirus (VDPV) outbreaks.

Ingestion presents the highest risk for facility personnel. Immunization with OPV or inactivated polio vaccine (IPV) prevents disease, but neither fully inhibits silent poliovirus infection nor reinfection of the gut. Ingestion of poliovirus may result from any laboratory operation, activity or incident that leads to the transfer of infectious particles to the gastrointestinal tract. Estimated infectious doses (ID_{50}) by ingestion, based on studies with infants and children, are $\pm10^{1}$ $CCID_{50}$ for wild polioviruses and $\pm10^{3}$ $CCID_{50}$ for Sabin strains. Immunized adult laboratory workers are likely more resistant than immunologically naïve children, but resistance is dose related and may be overcome by ingesting sufficient poliovirus particles. Droplets created by sprays, spills and the splash of poliovirus cell cultures (10^{8} $CCID_{50}$) and concentrates (10^{11} $CCID_{50}$) constitute the highest personnel exposure risks (Figure A3.1).

Inhalation, defined as exposure to small particle aerosols of <5 µm (droplet nuclei) deposited predominately in the lower respiratory tract, has been identified as a possible route of infection for poliovirus. The respiratory tract appears not to be a significant portal of entry. Unresolved, however, is whether small particle aerosols deposited in the lower respiratory tract may initiate alimentary tract infections through mucociliary transport to the pharyngeal region. Inhalation risks may be further reduced in facility environments maintained at low relative humidity (<50%). Antibodies acquired through immunization greatly reduce infection risks from injection or breaks in skin or mucous membranes.

Figure A3.1: Estimated poliovirus content and infectious dose[19]



Community members may be exposed to infectious agents from the laboratory through (1) workers' contaminated skin or clothing or unrecognized infection; (2) the release of contaminated air; (3) contaminated effluents and waste water recovered from secondary sewage treatment plants; (4) the uncontrolled transport of infectious material; (5) solid waste transported to landfills; (6) contaminated equipment or materials removed from the facility; (7) the escape of infected animals; and (8) a theft or deliberate release of infectious agents from a facility. Exposure risks through routes 4-7 are low for poliovirus facilities that adhere to international regulations for the transport of infectious substances, those outlined in the *Good Laboratory Practice* handbook and the WHO guidelines on *Good Manufacturing Practice*, and likely low for the inhalation of contaminated air effluent where facilities maintain low relative humidity environments and exhaust air away from direct human exposure. Exposure risks through the ingestion of effluents range between high and low, depending on the poliovirus content of facility effluent, sewerage system size and integrity, and the potential for human consumption. Risks of community exposure are highest through facility personnel unknowingly contaminated or infected with poliovirus. IPV immunization of facility personnel may greatly reduce the risk of intra- and extra-household transmission.

[19] Estimated infectious doses (ID_{50}) are based on studies with infants and children. Immunized adult laboratory workers are likely much more resistant than immunologically naïve children. However, dose-related resistance may be overcome by ingesting sufficient poliovirus particles.

Effective poliovirus risk management is achieved by the careful assessment of exposure risks, the implementation of risk-appropriate personnel protection measures, and the quality operation of a facility designed to minimize the risk of poliovirus contamination and dissemination to the community. The main risk is the infection of laboratory workers by ingestion. Airborne transmission is conceivable but not demonstrated and infection through parenteral exposure such as needlestick is unlikely in immunized individuals.

MANAGEMENT SYSTEM ELEMENTS

Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no WPV)

CWA15793 Clause No.[20]	Biorisk Management Element No.	Requirements for Containment of OPV2/Sabin2 poliovirus materials	Requirements for Final containment of all OPV/Sabin poliovirus materials	Guidance
		Element 1 – Biorisk Management System The biorisk management system element examines the system and policy in place to manage laboratory biorisk. Effective management and organization are vital to the success of any activity, and management commitment and leadership lay the foundation upon which a solid biorisk management system is built. Management must have clear strategies and objectives from which roles and responsibilities are allocated, implemented and monitored. Without effective management commitment and appropriate organizational structures, all other initiatives aimed at managing risk will be ineffective. The way management thinks and acts has a major impact on performance. **Subelements** 1.1 Biorisk Management Policy 1.2 Objectives, Targets and Programme 1.3 Roles, Responsibilities and Authorities 1.4 Records, Documents and Data Control 1.5 Analysis of Data 1.6 Change Management 1.7 Consultation and Communication	1.8 Programme of Work 1.9 Work Planning and Capacity 1.10 Legal Requirements 1.11 Continual Improvement 1.12 Preventive Action 1.13 Control of Nonconformities 1.14 Inspection and Audit 1.15 Corrective Action 1.16 Contractors and Suppliers 1.17 Biorisk Management Review 1.18 Biorisk Management System	

[20] Clause numbers referenced from final CWA15793, 2011 published version

CWA15793 Clause No.[20]	Biorisk Management Element No.	Requirements for Containment of OPV2/Sabin2 poliovirus materials	Requirements for Final containment of all OPV/Sabin poliovirus materials	Guidance
	1	**BIORISK MANAGEMENT SYSTEM**		
	1.1	**Biorisk Management Policy**		
CWA 4.2.1	1.1.1	Actions taken by top management demonstrating commitment to the policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity) include: 1. development; 2. authorization; 3. signing.		Biorisk management should be stated clearly as part of the organization's health, safety, security and environment (HSE) policies. Depending on the relevance of biorisk management to the organization, the biorisk management policy should complement the general HSE policies. As appropriate, the biorisk management policy may be integrated into the organization's HSE policies.
CWA 4.2.1	1.1.2	The policy clearly states: 1. the overall biorisk management objectives; 2. a commitment to improving biorisk management performance.		The policy should require that all projects/work areas be assessed for risks and a full assessment be prepared before approval is given to commence work.
CWA 4.2.1	1.1.3	The policy is appropriate to the nature and scale of the risk associated with the facility and associated activities.		
CWA 4.2.1	1.1.4	The policy commits to: 1. protecting staff, contractors, visitors, the community and the environment from poliovirus materials that are stored or handled within the facility; 2. reducing the risk of the unintentional release of, or exposure to, poliovirus materials; 3. reducing the risk of the unauthorized intentional release of hazardous biological materials to an acceptable level; 4. complying with all legal requirements applicable to the poliovirus materials that will be handled or possessed, and with the requirements of this standard; 5. ensuring that the need for effective biorisk management takes precedence over all non-"health and safety" operational requirements; 6. informing all employees and relevant third parties effectively and communicating individual obligations with regard to biorisk to these groups;		The policy includes the need to conduct risk assessments and implement the required control measures.

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		7. improving biorisk management performance continually.		
	1.2	**Objectives, Targets and Programme**		
CWA 4.3.3.1	1.2.1	Documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization are: 1. established; 2. implemented; 3. maintained.		
CWA 4.3.3.2	1.2.2	Management has established the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.		The controls can be monitored by regular audits, by utilizing corrective-action reporting processes where problems have been identified, by investigating incidents and accidents and improving controls and their implementation, and by ensuring adequate resources are provided to maintain the effectiveness of the controls. Note: Refer to Element 2 – Risk Assessment.
	1.3	**Roles, Responsibilities and Authorities**		
CWA 4.4.1.1	1.3.1	Top management takes ultimate responsibility for the organization's biorisk management system.		Top management includes officers (Director-General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and directors of the organization. Overall responsibility for managing biorisk rests with top management but tasks may be delegated through the organization provided they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller organizations, one individual may hold more than one role described in this standard. It is important to define roles and responsibilities, have clear communication within the organization regarding actions that need to be taken, and establish who has the required authority.

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CWA 4.4.1.1	1.3.2	Top management ensures that roles, responsibilities and authority related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of polioviruses.		In assigning roles and responsibilities, potential conflicts of interest should be considered. This standard has identified roles that need to be covered in the organization and has only used titles to illustrate these roles; these titles may not be the same as those used in specific organizations.
CWA 4.4.1.1	1.3.3	Top management demonstrates its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.		Resources include human resources and specialized skills, organizational infrastructure, technology and financial resources.
CWA 4.4.1.2	1.3.4	A senior manager has been designated with the operational responsibility to oversee the biorisk management system.		Senior managers are those with significant operational, budgetary and personnel authority at the departmental or higher level, and may include members of top management.
CWA 4.4.1.2	1.3.5	The senior manager's functions in managing biorisk include: 1. providing appropriate resources to ensure the adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; 2. reporting to top management on the performance of the biorisk management system and any need for improvement; 3. ensuring the promotion of the biorisk management system throughout the organization; 4. instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively;		The senior management representative should be an individual with decision-making authority at a level whereby he/she can allocate resources and make decisions regarding the facility's biorisk management needs (including required resources to conduct risk assessments and other management and administrative activities) independently of the need to implement the programme of work.
CWA 4.4.1.3	1.3.6	A biorisk management committee has been constituted to act as an independent review group for biorisk issues associated with the poliovirus facility.		The biorisk management committee is often recognized as the institutional biosafety committee. Its role may be either a dedicated function or one that is addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management

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				adviser(s), the security manager and the occupational health professional. Others, such as the facility manager and/or worker and community representatives, may be included depending on the nature of the agenda or work.
CWA 4.4.1.3	1.3.7	The biorisk management committee reports to senior management and: 1. has documented terms of reference; 2. includes a representative cross section of expertise, appropriate to the nature and scale of the activities undertaken; 3. ensures issues addressed are formally recorded, and actions are allocated, tracked and closed out effectively; 4. is chaired by a senior individual; 5. meets at a defined and appropriate frequency, and when otherwise required.		The committee's functions should include: a. contributing to the development of institutional biorisk policies and codes of practice; b. approving proposals for new work or significant modifications to the potential risk associated with existing activities; c. reviewing and approving protocols and risk assessments for work involving polioviruses; d. reviewing information related to significant accidents or incidents, data trends, associated local or organizational actions and communication needs. The list of roles for the biorisk management committee is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.4	1.3.8	One or more competent individuals are designated to provide advice and guidance on biorisk management issues.		The competent individual providing advice and guidance on biorisk management is often recognized as a biological safety officer or biological safety adviser. This function should normally be regarded as an advisory position and not one directly responsible for managing biorisk, as that rests with those conducting and managing the work within the organization (e.g. the scientific director, principal investigator, department head, laboratory manager, group leader). The role and knowledge of the biorisk adviser are important to develop, implement, maintain and continually improve a biosafety and biosecurity programme based on a management system. The adviser should be competent to perform the role and be allocated sufficient time and other resources to do the job effectively.

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CWA 4.4.1.4	1.3.9	The biorisk management adviser's role is independent of the functions of those responsible for implementing the programme of work.		In the execution of their biorisk management duties, advisers should be independent from those responsible for implementing the programme of work and have direct access to the top management representative when necessary.
CWA 4.4.1.4	1.3.10	The biorisk management adviser: 1. reports directly to the responsible senior manager; 2. has delegated authority to stop work in the event that it is considered necessary to do so.		The biorisk management adviser's functions should include: a. verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed; b. advising or participating in the reporting, investigation and follow-up of accidents/incidents and, where appropriate, referring these to management and/or the biorisk management committee; c. ensuring relevant and up-to-date information and advice on biorisk management are made available to scientific and other personnel as necessary; d. advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security); e. contributing to the development and/or delivery of biorisk training activities; f. ensuring all relevant activities are performed in compliance with biorisk regulations, and the required biorisk authorizations for work are in place. The list of roles for the biorisk management adviser is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.5	1.3.11	One or more individuals with responsibility for the scientific programme within the facility have been designated with responsibilities relevant to biorisk management.		The scientific manager is responsible for managing the scientific programme within the facility on a day-to-day basis, and for implementing and monitoring biorisk controls in association with other facility personnel (e.g. adhering to policies and procedures,

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				monitoring staff performance and participation in inspections and audits). The individual would normally have an in-depth knowledge of the work programme and the facility, would be in a supervisory/management position and may be referred to as Head of Department, Principal Investigator, Laboratory Supervisor/Manager or Group Leader. Competence is required in technical/scientific aspects of the poliovirus materials being used and in their control, and in the management of the facility, its personnel and systems. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.5	1.3.12	The scientific management functions include: 1. ensuring all work is conducted according to established policies and guidelines described in this standard; 2. supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; 3. planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; 4. ensuring required authorizations for work are in place; 5. ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and the required control measures are in place; 6. ensuring all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).		
CWA 4.4.1.6	1.3.13	The organization has access to appropriate occupational health expertise.		The occupational health professional would normally be a medical doctor or occupational health nurse with an understanding of the poliovirus materials handled within the facility.

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				The role should include providing input into risk assessment from a worker's health perspective, advising on first aid/ emergency treatment measures and follow-up, liaising with external health-care providers, and coordinating medical examinations, surveillance and vaccination programmes. The occupational health professional's roles and responsibilities should be determined in light of requirements set out in this standard.
CWA 4.4.1.6	1.3.14	The organization has established an occupational health programme commensurate with the facility's activities and risks.		
CWA 4.4.1.7	1.3.15	One or more facility managers have been appointed with responsibilities relevant to facilities and equipment, determined according to requirements set out in this polio biorisk management standard.		The facility manager would normally be an engineer or a person with an in-depth knowledge of laboratory facilities, containment equipment and buildings. The role should include providing input into risk assessment from a facility perspective, coordinating building and maintenance work, and liaising with contractors. The roles and responsibilities of the facility management personnel should be determined in light of requirements set out in this standard. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.8	1.3.16	A security manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.		The security manager would normally have an in-depth knowledge of laboratory and facility security, should liaise with other personnel (e.g. the biorisk management adviser) and implement effective and proportionate laboratory biosecurity measures, based on the biological risk. The role should include providing input into risk assessment and management from a security perspective. The security personnel's roles and responsibilities should be determined in light of requirements set out in this standard.

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CWA 4.4.1.9	1.3.17	In laboratories where animals are kept, an animal-care manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.		The animal-care manager would normally have an in-depth knowledge of animal handling, and zoonotic and animal diseases. The animal-care manager should liaise with other personnel (e.g. biorisk management adviser, occupational health professional) to implement effective and proportionate laboratory biosafety and biosecurity measures. A qualified veterinarian should be available for additional advice. The role should include providing input into risk assessment and management from an animal-care perspective.
	1.4	**Records, Documents and Data Control**		
CWA 4.5.2	1.4.1	Records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this polio biorisk management standard.		Where appropriate, documents should be identified and controlled based on the nature of the work and need for record-keeping.
CWA 4.5.2	1.4.2	Records, documents and data are handled in such a way that they remain legible, readily identifiable and retrievable. Documented records are maintained in paper or electronic form for a minimum of 10 years from the day of withdrawal and should be available for review during national certification/WHO verification procedures.		Controlled documents may include: a. risk assessments, standard operating procedures (SOPs) and safety manuals; b. job hazard analyses and charts of authority; c. design records and commissioning/test plans, maintenance plans and records, and all associated data; d. audit and inspection checklists; e. laboratory biosecurity manuals and risk assessments, authorizations and other security documents; f. training records; g. containment equipment certifications. The list of controlled documents is not exhaustive but includes some of the main areas that should be formally recorded and subject to document control. Data should be construed as documents in this context. A procedure should be established

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				to define the controls needed for the identification, storage, protection, retrieval, retention period and disposal of records. A procedure should be established to define the controls needed for the approval of documents prior to their issue or public release, to ensure sensitive information such as the specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls needed for the review, update and reapproval of documents, and for the control of change and revision process.
	1.5	**Analysis of Data**		
CWA 4.5.1	1.5.1	Appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.		The analysis should include data generated as a result of monitoring, measurement, audits and analysis, and from other sources. Such analyses should be conducted at least annually, and more often if justified by the risks and scope of operations. The results of the analysis should be applied in the management review.
	1.6	**Change Management**		
CWA 4.4.4.4	1.6.1	All changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.		These changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include an evaluation of the effect of the changes on the risk assessment. Examples of changes that should be subject to the change management process include: a. modifications to buildings and equipment or their operation, which could or would have an effect on biorisk; b. introduction of altered staffing arrangements (such as the temporary presence of on-site contractors or students, temporary reassignments of personnel);

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				c. changes to the programme of work, including alterations to workflow or volume, which could or would have an effect on biorisk; d. alterations to SOPs, including significant changes in materials or reagents; e. modifications to entry/exit protocols; f. modifications to personnel policies and visitor protocols; g. modifications to disinfection, decontamination and other waste management methodologies; h. changes associated with the provision and use of personal protective equipment (PPE).
	1.7	**Consultation and Communication**		
CWA 4.4.4.3	1.7.1	Relevant biorisk information related to an organization's activities is communicated to and from employees and other relevant parties.		The organization should implement mechanisms to ensure relevant and current information that can potentially affect workers and others is defined and delivered effectively at appropriate intervals. This could entail regular team meetings and briefings in the workplace, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others, including: a. local, national and international governmental organizations; b. relevant regulatory agencies; c. certifiers; d. emergency services and health-care providers; e. contractors and suppliers (e.g. cleaners, maintenance providers, security personnel); f. local community representatives (e.g. through a community liaison committee). Systems should be put in place to identify existing or emerging

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				technologies or other relevant information related to the containment of the poliovirus materials being handled or stored. This information should be shared with relevant staff through appropriate media, including the circulation of appropriate signage, documents and team briefings, and the maintenance of reference libraries and other sources of information.
CWA 4.4.3	1.7.2	Employee involvement and consultation arrangements are documented.		
CWA 4.4.3	1.7.3	Personnel have access to adequate and up-to-date information about the organization's biorisks.		
	1.8	**Programme of Work**		
CWA 4.4.4.3	1.8.1	The programme of work for the facility is defined, documented and reviewed.		The programme should include the nature of the activities authorized to be conducted in the facility and their definitions (e.g. diagnostics, research, small scale/large scale). All activities associated with the work programme should be specified and supported by formal SOPs approved in line with the requirements for controlled documents, as defined by this standard. Any changes to the programme of work should be subject to a formal change management process.
CWA 4.4.4.3	1.8.2	Criteria are established for work that requires prior approval.		
	1.9	**Work Planning and Capacity**		
CWA 4.4.4.3	1.9.1	Sufficient resource capacity and capability are available to manage workflow, whether planned or unplanned.		The resources needed to implement and maintain the biorisk management system and continually improve its effectiveness should be determined and provided.
	1.10	**Legal Requirements**		
CWA 4.3.2	1.10.1	The organization ensures that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements		The organization should adopt measures to identify the facility's legal and other requirements related to the poliovirus materials

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		include national/federal, regional/state, provincial, city and local regulations with which the organization must comply.		to be held and used, but also to other regulations including, for example, worker protection and rights, environmental impact, and general health and safety (e.g. fire, electrical). Monitoring for new and upcoming requirements, as well as those that already exist, is needed. This information should be kept up to date and the requirements should be incorporated into the facility's biorisk management system.
	1.11	**Continual Improvement**		
CWA 4.1.2	1.11.1	The organization continually improves the effectiveness of the biorisk management system through: • the policy; • its objectives; • the self-audit programme; • audit results; • the analysis of data; • the risk assessment; • corrective and preventive actions; • the management review.		The organization should strive to continue developing and refining the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved by setting objectives and giving targets to those working within the facility and by monitoring progress to ensure the objectives are achieved.
	1.12	**Preventive Action**		
CWA 4.5.4.4	1.12.1	Action is taken to identify and eliminate the causes of potential nonconformities to prevent their occurrence.		A procedure should be established to define requirements for: a. determining the potential nonconformities and their causes; b. evaluating the need for action to prevent the occurrence of nonconformities; c. determining and implementing the action needed; d. recording the results of action taken; e. reviewing the preventive actions taken.
CWA 4.5.4.4	1.12.2	Preventive actions are appropriate to the effects of the potential nonconformities.		

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	1.13	**Control of Nonconformities**		
CWA 4.5.4.2	1.13.1	Situations that do not conform to the requirements of this polio biorisk management standard are identified and controlled to prevent undesirable consequences.		The controls and related responsibilities and authorities needed to deal with nonconforming situations should be defined in a procedure.
CWA 4.5.4.2	1.13.2	Records are maintained of the nature of the nonconformity and any subsequent action taken.		
	1.14	**Inspection and Audit**		
CWA 4.5.5	1.14.1	An inspection and audit programme is conducted that is appropriate to the risk associated with the facility.		Inspections may be frequent checks of specific areas, conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels/concentrations, air exchange rates/ maintenance of directional air flow), or may be more extensive but less frequent inspections of laboratories, facilities or other operations. Random, unannounced inspections and inventory audits can help ensure compliance at all times and not just in time for scheduled inspections. Audits should be performed by competent individuals unaffiliated with the audited activity. Records of inspection/audit findings should be maintained, including action taken to close out any nonconformities or pursue improvement opportunities.
CWA 4.5.5	1.14.2	Inspections and audits are conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and the requirements of this polio biorisk management standard, and if it is effectively implemented and maintained. *National inspection and audit.* An inspection and audit programme is conducted regularly (e.g. annually) by national authorities to determine if the biorisk management system conforms to the requirements of this standard and is functioning properly, and to ensure necessary corrective actions are taken and verified without undue delay.		

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		WHO inspection and audit. Top management ensures that information is made available in English according to WHO review team needs, that it is accessible for the periodic comprehensive WHO review of the poliovirus facility and that deficiencies identified by the process, as outlined in 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)*, are addressed to the satisfaction of WHO.		
CWA 4.5.5	1.14.3	Management responsible for the area being inspected/audited ensures that any actions are taken without undue delay to eliminate detected nonconformities and their causes.		
CWA 4.5.5	1.14.4	Follow-up activities include: 1. verification of the actions taken; 2. reporting of the verification results.		
	1.15	**Corrective Action**		
CWA 4.5.4.3	1.15.1	To prevent the recurrence of any nonconformities, action is taken to eliminate their causes using the requirements of the polio biorisk management standard for *poliovirus-essential facilities holding only OPV/ Sabin poliovirus materials.*		A procedure should be established to define requirements for: a. reviewing the nonconformities; b. determining the cause of nonconformities; c. evaluating the need for action to ensure nonconformities do not recur; d. determining and implementing the action needed; e. recording the results of action taken; f. reviewing the corrective actions taken.
CWA 4.5.4.3	1.15.2	Corrective actions are appropriate to the effects of the nonconformities encountered.		
	1.16	**Contractors and Suppliers**		
CWA 4.4.4.8.6	1.16.1	Purchases (including services) conform to specified requirements.		

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CWA 4.4.4.8.6	1.16.2	Controls on purchases (including services) are applied depending on the potential impact on the biorisk involved.		
CWA 4.4.4.8.6	1.16.3	Suppliers are evaluated and selected based on their ability to provide products/services that meet the requirements of this polio biorisk management standard.		While not all suppliers will provide products/services that may have an impact on biorisk, many may. Suppliers that should be considered include, but are not limited to, those that provide: a. cleaning services; b. laboratory equipment; c. waste management or disposal services; d. information technology support services; e. equipment and facility maintenance services; f. security services.
CWA 4.4.4.8.6	1.16.4	Criteria for selection, evaluation and re-evaluation are established.		
CWA 4.4.4.8.6	1.16.5	Records are maintained of evaluation results and any necessary actions arising from the evaluation.		
	1.17	**Biorisk Management Review**		
CWA 4.6.1	1.17.1	Top management reviews the organization's biorisk management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness.		The management review should be conducted regularly, at a frequency determined by the needs of the organization, but at least annually.
CWA 4.6.1	1.17.2	The review includes: 1. assessing opportunities for improvement; 2. determining the need for changes to the system, procedures, policies and objectives.		Review input should include information on: a. the results of audits; b. compliance with SOPs and work instructions; c. the status of risk assessment activities; d. the status of preventive and corrective actions; e. follow-up actions from previous management reviews; f. changes that could affect the system; g. recommendations for improvement; h. the results of accident/incident investigations.

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CWA 4.6.1	1.17.3	Records are maintained from the management review.		The review's output should include decisions and actions related to: a. improvement of the biorisk management system's effectiveness; b. improvement related to the requirements and risk assessments; c. resource needs.
	1.18	**Biorisk Management System**		
CWA 4.1.1	1.18.1	The organization has established, documented, implemented and maintains a biorisk management system according to the requirements of this polio biorisk management standard.		
		Element 2 – Risk Assessment The Risk Assessment element looks at how organizations define risk and implement effective mechanisms to identify, assess and manage those risks. Areas addressed include how to ensure consistency and transparency in assessing risk across the organization, without placing an unnecessary burden on specialists and support staff. This element is regarded as a foundation upon which the others must be based. **Subelements** 2.1 Process, Methodologies and Procedures 2.2 Assessment Timing and Scope 2.3 Roles and Responsibilities 2.4 Hazard Identification 2.5 Risk Assessment 2.6 Risk Control		
	2	**RISK ASSESSMENT**		
	2.1	**Process, Methodologies and Procedures**		

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CWA 4.3.1.1	2.1.1	The organization ensures that a risk assessment system is established, implemented and maintained according to this polio biorisk management standard.		
CWA 4.3.1.1	2.1.2	The risk management system's performance is reported to senior management for review and as a basis for improvement.		
CWA 4.4.4	2.1.3	The organization has identified those operations and activities associated with possible biological risk and where control measures are to be applied.		
CWA 4.4.4	2.1.4	Activities associated with possible biological risk, including maintenance, are carried out under specified conditions.		
	2.2	**Assessment Timing and Scope**		
CWA 4.3.1.2	2.2.1	The approach to risk assessment is defined according to its scope, nature and timing so it is proactive rather than reactive.		The following should trigger either a new risk assessment or the review of an existing one: a. commencement of new work or changes to the programme of work, including the introduction of new biological agents or alterations to workflow or volume; b. new construction/modifications to laboratories, plants and equipment or their operation; c. introduction of altered and unplanned staffing arrangements, including those concerning contractors, visitors and other non-core personnel; d. significant alterations to SOPs or working practices (e.g. disinfection/waste management methodologies, PPE provision, usage entry, exit protocols); e. unexpected events that may be relevant to the management of biorisks; f. actual or potential nonconformity with internal/external rules and regulations (e.g. the introduction of new legislation or major accident exposure);

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				g. consideration of emergency response and contingency planning requirements; h. the existing management system review process (e.g. annually or at another appropriate and predetermined frequency). Many defined methodologies and approaches are available to conduct hazard identification, risk assessment and control; the approach taken will vary depending on the nature of the situation and the level of detail required. One framework that organizations may consider adopting is outlined in Figure 1 of CWA15793, 2011 (GAPIII, Annex 5).
	2.3	**Roles and Responsibilities**		
CWA 4.3.1.1	2.3.1	Resource requirements have been identified and adequate resources provided, including assigning trained personnel to management, work performance and verification activities, including internal review.		The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need the organizational freedom and authority to: a. initiate action to prevent or reduce the adverse effects of risk; b. control the further treatment of risks until the level of risk becomes acceptable; c. identify and record any problems related to managing risks; d. initiate, recommend or provide solutions through designated channels; e. communicate and consult internally and externally as appropriate.
	2.4	**Hazard Identification**		
CWA 4.3.1.3	2.4.1	The hazards associated with proposed work are: 1. identified; 2. documented.		The first stage in the risk management process is to identify all hazards relevant to biorisk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and risk management.

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				A hazard may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting) or a material (in this case, the principal hazard is most likely to be a poliovirus, but others include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is its potential to cause harm, regardless of how likely such an occurrence might be. Biological hazards should be identified and assessed in relation to their potential damage to humans, animals and the environment. Where hazardous materials are classified into hazard or risk groups based on international and/or foreign country classification schemes, local diverging needs and constraints should be considered. A hazard identification exercise should use information that includes: a. group experience and knowledge; b. external or specialized expertise not found in the facility; c. results of previous assessments; d. surveys of previous accidents/incidents; e. hazardous materials data; f. information on hazardous organisms; g. guidelines and codes of practice; h. facility drawings; i. SOPs, manuals, etc.; j. process maps. Defined methodologies and approaches are available to conduct hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with

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				the facility and its activities. Hazard identification should be appropriate in nature and structure, and recorded to a level whereby others can review the process.
	2.5	**Risk Assessment**		
CWA 4.3.1.4	2.5.1	Suitable methodologies for assessing and recording risks are: 1. identified; 2. implemented; 3. maintained. Risk assessments are documented.		The risk assessment should categorize risks to identify those that need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels, should be defined and used in the assessment. Such a classification can be achieved, for example, by using a risk matrix that identifies likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate. Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. In conducting the assessment, due consideration should be given to the inherent risk from polioviruses (e.g. from risk grouping descriptions, material safety data sheets). After defining and implementing control measures, the risks should be reviewed to decide whether the remaining risk is acceptable or additional controls need to be identified and implemented.
	2.6	**Risk Control**		
CWA 4.3.1.5.	2.6.1	Suitable methodologies for allocating actions that result from risk assessments, including timelines, responsible persons and associated reporting and approval mechanisms, are: 1. identified;		The risk management approach should have a control plan that includes: a. who is responsible and accountable for implementing the plan;

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		2. implemented; 3. maintained.		b. what resources are to be used (e.g. people, budget); c. a timetable for implementation; d. details of the mechanism and frequency of reviewing compliance with the plan. Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls or the reliance on PPE.
		Element 3 – Poliovirus Inventory and Information The Poliovirus Inventory and Information element examines the systems in place to identify, record and review the organisms stored, received and transported from a facility. The level of detail and nature of the system depends on the pathogens being held, and ranges in complexity from simple lists to secure databases. This element also examines the way materials are stored, including segregation, labelling systems and controls of stocks of cultures. **Subelements** 3.1 Inventory 3.2 Information and Records 3.3 Transfer of Poliovirus Materials 3.4 Monitoring and Control		
	3	**POLIOVIRUS INVENTORY AND INFORMATION**		
	3.1	**Inventory**		
CWA 4.4.4.2	3.1.1	An accurate and up-to-date poliovirus inventory is established and maintained.		The inventory process should be based on risk and include: a. identifying all poliovirus materials held, including cultures,

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				specimens and other sources (e.g. infected tissues/samples or animals); b. storing poliovirus material within the containment perimeter of the poliovirus facility, ensuring stored samples of wild and Sabin poliovirus materials are segregated from each other and other isolates, cell lines, cultures or other materials that could be subject to cross-contamination or misidentification; c. ensuring the movement of poliovirus materials to and from storage meets the standards of element 15 (Transport Procedures); d. ensuring the surfaces of all storage vessels are decontaminated with a validated method for inactivating polioviruses; e. restricting access to poliovirus materials to authorized individuals with a demonstrable legitimate need; f. implementing effective physical security measures according to risk (e.g. locks, alarms, access controls); g. developing and maintaining a reliable sample identification system; h. segregating and storing poliovirus materials according to risk; i. determining what materials should be controlled (e.g. seed stocks, working stocks, infected animals) and what level of information should be captured in the inventory for these materials.
	3.2	**Information and Records**		
CWA 4.4.4.2	3.2.1	Records related to the poliovirus inventory are: 1. current; 2. complete; 3. stored securely with adequate backup provision.		Inventory information should include: a. the name(s) and contact information of the individuals(s) responsible for the poliovirus material, and the details of other personnel with access to the poliovirus materials or the immediate area based on the level of risk;

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				b. restricted access to the detailed inventory records to those individuals whose work requires access to that information; c. legible and robust identification numbers and other relevant identifiers; d. records of quantities/volumes of poliovirus materials at an appropriate level and based on risk (number of containers/vials or applicable equivalent), exact location of storage, and ability to account for materials at all times; e. origin, including geographical source and date of collection; f. records of materials removed from storage to conduct work, and the fate of those materials and any newly developed stocks (consumed, destroyed, removed from the facility, returned to storage in location X) following the completion of the work.
	3.3	**Transfer of Poliovirus Materials**		
CWA 4.4.4.2	3.3.1	Transfers of poliovirus materials between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of risk.		Controls should be put in place to ensure all the necessary checks and documented assurances are received to guarantee that requests for poliovirus materials originate from legitimate facilities and individuals. Material may only be brought into the facility or sent elsewhere if authorized by those responsible for the facility. For materials deemed to be of high risk, more stringent controls, including shipment tracking and the verification of receipt, are necessary.
	3.4	**Monitoring and Control**		
CWA 4.5.3	3.4.1	The inventory is reviewed at predetermined intervals based on risk, and at a level and frequency whereby materials can be accounted for in an appropriate manner.		The nature of the inventory and associated controls should be based on the nature of the material held and on the risk of harm should it be misplaced or removed with the intention of misuse. Poliovirus inventories will be monitored so that materials missing, unaccounted for or no longer needed are identified,

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				consistent with the goal of reducing amounts of live poliovirus materials to the lowest level possible. An inventory review will be conducted at least annually.
CWA 4.5.3	3.4.2	Measures are put in place to minimize the quantities of poliovirus materials in the inventory.		The organization should demonstrate proactive measures to reduce risk through the elimination, substitution or minimization of volumes/quantities of poliovirus materials used, and the number of manipulations conducted. Procedures should be in place to investigate potentially missing poliovirus materials.
		Element 4 – General Safety The General Safety element examines the processes in place to make sure hazards associated with the personnel's work in the facility are identified and managed while addressing their implications for biorisk. Both a preventive and proactive approach should be taken to establish measures to identify, detect, mitigate and respond to emergencies related to general safety, such as fire, electricals, radiation, chemicals, animal care and pressurized equipment. **Subelement** 4.1 General Safety		
	4	**GENERAL SAFETY**		
	4.1	**General Safety**		
CWA 4.4.4.1	4.1.1	A formal process is in place to identify and manage risk associated with general safety.		The organization should adopt a preventive and a proactive approach to managing such sources of risk, both to protect workers from the direct hazards associated with their work and to address the implications for biorisk in the event of an accident/ incident resulting from such sources. Measures should be identified and implemented to detect, mitigate and respond to emergencies, taking into consideration the potential implications

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				for poliovirus control in such measures. Issues addressed should include but are not limited to: a. general laboratory safety; b. fire safety; c. electrical safety; d. radiation safety; e. chemical safety; f. the use of gasses (including risk of asphyxiation); g. hot work and cold work; h. equipment under pressure; i. laboratory animal care and use; j. general housekeeping, including storage requirements and tidiness, and the control of general waste.
		Element 5 – Personnel and Competency The Personnel and Competency element covers the processes in place to ensure that people with appropriate qualifications and backgrounds are recruited, that they are subsequently trained in all aspects of the work programme, and that their competency is assessed and monitored in a structured way. Other issues dealt with include how capacity issues are addressed and staff turnover is managed to ensure the organization is not left vulnerable when critical roles are vacated. **Subelements** 5.1 Recruitment 5.2 Training 5.3 Competence 5.4 Continuity and Succession Planning 5.5 Exclusion		
	5	**PERSONNEL AND COMPETENCY**		

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	5.1	**Recruitment**		
CWA 4.4.2.1	5.1.1	Qualifications, experience and aptitudes related to biorisk are considered as part of the recruitment process.		Prior to employing a candidate, the organization should ensure that: a. all personnel in the poliovirus facility should be subject to a formal selection process, including relevant background checks based on risk (e.g. employment references, security checks); b. appropriate controls are implemented should existing employees be transferred to areas where there may be an increased risk profile; c. all personnel entering areas with potential for exposure to poliovirus materials accept compliance with the health-care standards outlined in element 9 (Health Care), specifically including immunization with inactivated polio vaccine (IPV) every three years and an annual medical examination that includes the determination of poliovirus antibody titres; d. an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students), and measures are implemented to ensure they are applied where necessary.
	5.2	**Training**		
CWA 4.4.2.4	5.2.1	Requirements and procedures for biorisk-related training of personnel are identified, established and maintained.		Procedures should: a. define biorisk training needs, including training specific to the characteristics of poliovirus and the procedures for minimizing risk within the facility, for all persons working within the containment perimeter as well as all those who may need to enter the perimeter, including medical support staff, maintenance staff and emergency responders; b. provide the required biorisk training;

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				c. determine the effectiveness of the biorisk training; d. provide refresher biorisk training; e. restrict personnel from performing tasks for which they are not trained; f. maintain adequate records. Training should include raising awareness of biorisk issues among the personnel, including the relevance of human factors in biorisk management.
	5.3	**Competence**		
CWA 4.4.2	5.3.1	Personnel who have responsibilities and/or perform tasks within the poliovirus facility that may impact biorisk management in the workplace are competent to do so.		Competence is defined in relation to appropriate education, training and/or experience, together with a demonstrable ability to perform the task in a safe/secure manner. Procedures should: a. define competency needs; b. lead to the successful completion of the required training; c. lead to the ability to perform tasks under supervision and unsupervised; d. restrict personnel who have not demonstrated competence from performing tasks for which they are not eligible; e. maintain adequate records. No worker should be exempt from demonstrating competence, irrespective of rank, experience or background.
CWA 4.4.2	5.3.2	Competence levels are judged on appropriate: 1. education; 2. training; 3. experience.		
CWA 4.4.2	5.3.3	The organization has defined required levels of competency.		

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CWA 4.4.2	5.3.4	Records are maintained that show staff members have attained and demonstrated those levels of competency.		
CWA 4.4.2	5.3.5	Personnel who conduct activities within the facility are under close supervision until they have demonstrated competency.		
	5.4	**Continuity and Succession Planning**		
CWA 4.4.2.3	5.4.1	Adequate backup and contingency measures are in place to address the need for continuity and succession planning.		The organization should identify roles and individuals that require a substitute, ensuring the integrity of the facility is not compromised through short- or long-term absence. Such measures should include succession planning for personnel (technical, management and scientific, including contractors) to guarantee that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of that individual's departure or unavailability.
	5.5	**Exclusion**		
CWA 4.4.4.7.3	5.5.1	Measures are put in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility, where deemed necessary through risk assessment.		The measures should: a. remove access to the facility (e.g. taking away passes, changing locks and keys and access codes, and other security devices); b. withdraw access to information related to the facility, including documentation, computerized records and data; c. allow the immediate physical removal of personnel if deemed necessary.
		Element 6 – Good Microbiological Technique The Good Microbiological Technique element examines how an organization identifies appropriate microbiological techniques and controls, and how they are implemented and reviewed. A major part of this element is the development of a biosafety or operations manual, which identifies hazards that may be encountered and specifies practices		

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		and procedures designed to minimize or eliminate risks. **Subelement** 6.1 Good Microbiological Technique		
	6	**GOOD MICROBIOLOGICAL TECHNIQUE**		
	6.1	**Good Microbiological Technique**		
CWA 4.4.4.5.1	6.1.1	All personnel handling poliovirus materials are competent in good microbiological techniques.		
CWA 4.4.4.5.1	6.1.2	Appropriate resources (including time and equipment) are available to ensure good microbiological techniques are adhered to effectively.		As appropriate, procedures should address risks associated with but not limited to the following: a. the handling of infectious poliovirus materials; b. animal handling; c. centrifugation; d. the control of needles and sharps; e. the correct use of vacuum pumps; f. culture, purification and storage techniques; g. the minimization/containment of aerosols; h. pipetting; i. sonication and other mechanical forms of cell/tissue disruption; j. the use of biological safety cabinets (BSCs); k. the use of disinfectants, including spill control, routine decontamination, hand washing and showering. This list is not exhaustive and identifies only some activities that may be employed during typical laboratory work. These activities should be undertaken in association with appropriate procedures and working practices to ensure the control measures are effective under all foreseeable and credible operating scenarios. Appropriate

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				control measures should be identified during risk assessments and designed to minimize poliovirus exposure, including: a. the required use of devices, e.g. BSCs, which are validated to maintain primary containment for all procedures using live poliovirus; b. the substitution of Sabin with further attenuated strains (as these become available) when live virus use is required.
		Element 7 – Clothing and Personal Protective Equipment (PPE) The Clothing and PPE element examines how an organization ensures that staff is provided with the right tools to minimize potential exposures, and that they know how and when to use them. This element specifically addresses the characteristics of some key items, for example the use of respirators and positive pressure suits, but also considers other commonly used items, including gloves, laboratory coats and footwear. **Subelement** 7.1 Clothing and Personal Protective Equipment (PPE)		
	7	**CLOTHING AND PERSONAL PROTECTIVE EQUIPMENT (PPE)**		
	7.1	**Clothing and Personal Protective Equipment (PPE)**		
CWA 4.4.4.5.4	7.1.1	PPE needs are identified.		Measures in place should include: a. ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback); b. ensuring all personnel who must use PPE, including scientific staff, visitors and contractors, are identified and supplied with correctly fitting equipment and clothing; c. explicitly addressing the selection and use of PPE in SOPs, training and competency assessments;

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				d. defining and conducting an appropriate programme to ensure routine checks and the maintenance of PPE are defined and carried out; e. defining and addressing the need for and provision of replacement and spare PPE; f. identifying and controlling the hazards associated with PPE itself (e.g. impaired dexterity or visibility); g. providing adequate PPE for use during both normal and emergency working conditions; h. ensuring procedures are in place for the cleaning and, if appropriate, the validated decontamination of used PPE, including safe storage prior to decontamination. PPE should be used in conjunction with, but never as a substitute for, reasonable and appropriate administrative and engineering controls. PPE should be used in accordance with established standards and manufacturer specifications. Employers should make PPE available to employees at no cost.
CWA 4.4.4.5.4	7.1.2	Suitable equipment is specified, made available, used and maintained appropriately within the facility.		Poliovirus-specific PPE needs should be determined by a risk assessment and may include the use of face shields, goggles, gloves, masks, HEPA-filtered respirators and clothing strictly dedicated for use within the containment perimeter, including solid front gowns or other clothing protecting the body from exposure.
		Element 8 – Human Factors The Human Factors element is critical in any biorisk management programme, addressing issues as diverse as raising awareness of biorisk issues to initiating change management, and measuring and improving an organization's biorisk culture. Creating an environment where people		

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		are confident in reporting what has gone wrong and eliminating a "blame culture" are also addressed. **Subelement** 8.1 Human Factors		
	8	**HUMAN FACTORS**		
	8.1	**Human Factors**		
CWA 4.4.4.7	8.1.1	The organization has established and maintains a programme to address risk associated with human behaviour, including the management of how workers interact with the facility and its equipment.		The organization should ensure that factors associated with behaviours, and the need for individual support and communication, are managed responsibly, both to protect workers from direct hazards and to ensure they can function optimally within the facility. Many laboratory incidents are caused by inappropriate behaviour or human frailties, and a preventive and proactive approach to managing risk associated with the individual should be pursued, including the specific inclusion of such issues in risk assessments. The use of competent experts in assessing this area should be considered. Measures should be put in place to address: a. human reliability and behavioural safety, including adherence to procedures; b. team building and motivation; c. communication, consultation and feedback; d. conflict management and resolution; e. the management of stress and fatigue; f. empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified; g. access to counselling;

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				h. the avoidance of a "blame culture", including willingness to report accidents, incidents or unsafe conditions/behaviours, and protection of workers who do so; i. ergonomics, including equipment and work practice design to take account of individual needs; j. respect for individual privacy and dignity.
		Element 9 – Health Care The Health Care element evaluates the systems in place to protect workers from injuries and illnesses resulting from exposures to biological agents or their products, and how they are supported in the event of an accident. Subject areas covered include exposure control, health care and monitoring, immunization and the availability of competent first aid and external assistance. **Subelements** 9.1 Worker Health Programme 9.2 Vaccination of Personnel 9.3 Medical Emergencies		
	9	**HEALTH CARE**		
	9.1	Worker Health Programme		
CWA 4.4.4.6	9.1.1	The organization ensures that the risk to worker health, and that of other personnel whose health could be directly impacted by exposure to poliovirus materials, is managed effectively, including through preventive and protective measures.		The programme should address the needs of all individuals associated with the facility, including providing assurance that contractors and visitors receive the required level of protection in line with the activities they perform, as well as safeguarding workers' families.
CWA 4.4.4.6	9.1.2	The requirements of the health surveillance programme are determined by a defined health hazard identification and risk assessment process that		The programme may consult relevant personnel, including: a. the biorisk management adviser;

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		involves all relevant personnel.		b. the occupational health professional; c. facility personnel and employee representatives; d. external experts, including emergency responders; e. biorisk management committee members; f. veterinary and animal-care facility staff; g. human resource representatives; h. the communicable disease specialist; i. scientific management. Personnel considered to have significant risk of exposure should be identified and their health-care needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation/testing in the event of exposure. The individual's health and immune status, including an assessment of polio antibody titres as described under subelement 9.2.3, should be considered, and periodic checks appropriate to work conditions should be established. Although the primary focus of the assessment is exposure to the poliovirus materials being handled, other conditions that could impact personnel associated with the facility should also be addressed. These may include medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility/dexterity), the ability to safely use appropriate PPE, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status, substance abuse). Information covered by the worker health programme should be treated confidentially. All individuals should have

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				access to health-care consultation with either a corporate or institutional occupational health facility or an independent health-care provider, and be informed of the nature of any treatments/vaccinations they may receive and their inherent risks and benefits.
	9.2	**Vaccination of Personnel**		
CWA 4.4.4.6.1	9.2.1	Based on risk, the need for vaccination has been determined and covers groups identified as being potentially exposed to poliovirus.		Measures should be implemented when needed to identify non-responders to vaccination (depending on the vaccine's response rate) and a policy should be in place to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas with risk of exposure. Areas requiring vaccinations to enter should be posted. Visitors, contractors and other non-core personnel should provide evidence of vaccination or of established immunity in accordance with the above requirement. Based on risk, reasonable measures should be taken to ensure that the vaccinations have been given and current certificates are valid. This may include examining original certificates and cross-checking with medical practices responsible for administering the vaccine. The organization should ensure the required or recommended vaccines are made available to concerned personnel. Vaccination should be seen as a risk-mitigation strategy and its use should in no way infer that other controls, such as the use of good microbiological techniques or PPE, can be relaxed.
CWA 4.4.4.6.1	9.2.2	A vaccination policy has been defined and implemented.		
CWA 4.4.4.6.1	9.2.3	Access to laboratories or work is controlled for individuals until they comply with the vaccination policy.		The organization will ensure the availability of IPV for individuals associated with the facility, consistent with the objectives to:

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				a. restrict access to the containment facility to individuals who have demonstrable immunity to poliovirus (defined as annual verification of serum neutralizing antibody titres of 1:8 or greater against all three poliovirus types), including: – personnel assigned to work within the containment perimeter; – contractors, auditors and visitors who must enter the containment perimeter; – support personnel and contractors working immediately outside the containment perimeter (e.g. maintenance personnel, cleaning staff); b. administer an IPV booster every three years to all personnel mentioned above or in the event of an antibody titre determined to be <1:8 via annual testing; c. provide effective secondary population safeguards by an established programme of education and promotion to encourage acceptance of immunization by: – non-core facility personnel, including contractors; – workers' families/companions; – other groups in contact with the facility.
	9.3	**Medical Emergencies**		
CWA 4.4.5.2	9.3.1	A system is established to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers.		Procedures should ensure that adequate emergency planning is provided to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, to members of the broader community and to environmental conditions that may have been affected by the incident. It should include identifying emergency scenarios (e.g. involving an infected worker/family member) and necessary support measures (e.g. liaison with emergency services/

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				local authorities), and providing equipment and other resources required to manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained. Procedures should ensure that adequate first aid is available in relation to credible accident scenarios, as identified during risk assessments. The procedures should address the need for adequately trained personnel and their availability, as well as equipment and other materials that may be required to provide treatment. Procedures should ensure additional competent medical support is identified and made available (e.g. hospitals, isolation units).
		Element 10 – Emergency Response and Contingency Planning The Emergency Response and Contingency Planning element examines the structures and mechanisms in place to cope with working outside normal operating conditions, and how to react proportionally to emergency situations. Issues addressed include physical requirements, capacity in terms of personnel and facilities and of protective and rescue systems, emergency communications, decision-making authorities and the development and testing of emergency scenarios and simulations. **Subelements** 10.1 Emergency Scenarios 10.2 Emergency Response and Planning 10.3 Emergency Plans 10.4 Emergency Exercises and Simulations 10.5 Contingency Plans		

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	10	EMERGENCY RESPONSE AND CONTINGENCY PLANNING		
	10.1	Emergency Scenarios		
CWA 4.4.5.1	10.1.1	All credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.		To plan for emergencies, all credible emergency scenarios must be considered. It is unlikely that all potential scenarios will be credible, but all reasonable threats should be considered and recorded and, where appropriate, the rationale for dismissing any issue should be provided. Scenarios considered should include: a. an infected/potentially infected worker or other contact (e.g. family member, emergency responder or community member); b. accident or illness to a worker within the containment area and need for evacuation; c. fire; d. flood; e. breach of security; f. explosion; g. the potential loss of poliovirus through theft or any other reason; h. unexpected virulence (unknown biological agents or biological agents expected to be avirulent); i. physical facility and equipment failure, including a control system failure of the disinfection regime; j. utility failure including electricity, gas, steam and water supplies; k. a major spillage/aerosol release; l. environmental release; m. a natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics);

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				n. an act of terrorism or deliberate vandalism, extortion; o. intense media attention.
	10.2	**Emergency Response and Planning**		
CWA 4.4.5	10.2.1	Plans and procedures are established and maintained to: 1. identify the potential for incidents and emergency situations involving biological agents, toxins and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them.		
CWA 4.4.5	10.2.2	Emergency planning covers all aspects of biorisk and includes general safety, security and medical issues. A system is established to effectively manage a confirmed facility-associated poliovirus infection until the individual is free of poliovirus in stools for three consecutive days. This includes procedures for: 1. isolating infected individuals, particularly from children and the unimmunized; 2. collecting and disinfecting stool and associated waste; 3. educating families and frequent contacts on the risk posed by poliovirus infection and the procedures for isolation; 4. communicating with relevant national and local officials to evaluate the needs to implement community immunization response plans; 5. notifying WHO; 6. disinfecting areas potentially contaminated by infected individuals.		
	10.3	**Emergency Plans**		
CWA 4.4.5.2	10.3.1	Biorisks are taken into account when preparing and implementing emergency plans.		The organization should ensure that plans address the following needs at a minimum:

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		A system is established to effectively manage incidents that are determined by the evaluation/response team to be significant poliovirus exposures, including: 1. implementing full preventive measures by isolating individuals under evaluation from children and the unimmunized in particular, and securing stool and associated waste; 2. educating individuals under investigation, their family and close contacts on the risk of poliovirus infection to the community, the procedures for diagnosis and the precautionary measures required to prevent possible transmission; 3. initiating procedures to determine whether individuals are infected, by collecting and testing nose, throat and stool specimens daily for a minimum of seven days post-exposure.		a. identifying those responsible for devising, implementing and testing the control measures specified, along with ensuring their conclusions are effectively communicated to all relevant personnel; b. ensuring the legality and enforceability of proposed emergency response plans; c. responding during emergencies occurring outside working hours as well as those occurring during normal working hours; d. providing for periods of reduced staff availability (e.g. during weekends and holiday periods); e. ensuring emergency access/exit, including the ability to override access controls as appropriate; f. providing emergency exit routes that avoid evacuating people through containment areas; g. providing for the safe removal, transport, transfer, treatment and accommodation of contaminated persons and objects; h. informing visitors and contractors about emergency response plans and the possible consequences of exposure.
CWA 4.4.5.2	10.3.2	Control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency.		
CWA 4.4.5.2	10.3.3	Emergency plans are effectively communicated to all employees and relevant third parties, and tested with the goal of making everyone aware of their obligations.		In the event of an emergency situation, it may be necessary to involve parties external to the organization. Based on the credible scenarios identified, the organization should pinpoint such agencies to establish their role in responding to a given situation. The organization may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties on their role and any risk exposures they may face, and ensure their actions will not unnecessarily increase the risk associated with the emergency (e.g. uncontrolled use of water for fires). Contact

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				information should be documented and made available to personnel responsible for coordinating the emergency response activity. External agencies consulted may include: a. police and security services; b. fire services; c. ambulance and local hospitals/health-care providers; d. transport providers/couriers; e. local and national government officials; f. environmental authorities; g. WHO.
	10.4	**Emergency Exercises and Simulations**		
CWA 4.4.5.3	10.4.1	Structured and realistic emergency exercises and simulations, including security drills, are conducted at regular intervals based on risk, to test the plans, prepare personnel and learn from any good practices or deficiencies identified.		Exercises and simulations should be conducted to provide assurance that plans are effective and to learn from any lessons that arise. Exercises should be planned and every effort made to ensure they realistically represent the events simulated. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of an exercise should be documented and reviewed for lessons learnt, and feedback on performance should be provided to the appropriate personnel. Any resulting actions should be recorded and allocated to named individuals, and measures should be put in place to ensure they are closed out effectively.
	10.5	**Contingency Plans**		

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CWA 4.4.5.4	10.5.1	In the event of an emergency, adequate contingency measures are in place to ensure the safety and security of continued operations.		Normal operating conditions may be disrupted in the event of an emergency or unforeseen event. This could range from safely shutting down work during a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively, and contingency plans put in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems (e.g. power supplies), alternative means of decontaminating materials in the event of the failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shutdown of operations in extreme situations.
		Element 11 – Accident/Incident Investigation The Accident/Incident Investigation element addresses activities that define the facts and circumstances related to an event, determine the causes and develop remedial action to control biorisk and prevent recurrence. Often, chance is the only reason a property-damage accident or near-miss incident does not result in infection or personal harm. Likewise, chance alone often determines whether an accident's consequences are minor, serious or catastrophic. This element examines the organization's reporting and investigation system, whether the right people are involved and how corrective and preventive actions are implemented. **Subelement** 11.1 Accident/Incident Investigation		
	11	ACCIDENT/INCIDENT INVESTIGATION		
	11.1	**Accident/Incident Investigation**		

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CWA 4.5.4.1	11.1.1	Documented procedures are established and maintained to define, record, analyse and learn from accidents and incidents involving poliovirus materials.		Procedures should be put in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel. It may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed; it is essential that lessons be learnt and improvements made where possible. The accident/incident investigation process should include at a minimum: a. creating a culture of self-reporting incidents, including "near misses" and incidents that may trigger an investigation or emergency response; b. identifying those responsible for maintaining the accident/ incident reporting system; c. defining what constitutes an accident/incident and what triggers recording and reporting, with emphasis on events that may result in exposure to live poliovirus (e.g. sticks, spills, splashes, sprays, leaks, aerosol generating events); d. defining what constitutes a significant poliovirus exposure (e.g. ingestion) and thresholds for initiating procedures to determine whether individuals are infected; e. specifying required documentation to support the system, as well as the frequency and distribution of reports generated and communicated to relevant personnel; f. identifying the reports that will be generated, as well as their frequency and distribution; g. establishing a poliovirus incident evaluation/response team (composed of facility medical, public-health and polio-specific expertise) that determines whether an exposure is significant, reports its findings to the senior manager and recommends such actions as deemed necessary;

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				h. establishing and publicizing 24-hour accident/incident reporting channels, and identifying those responsible for maintaining the system; i. ensuring an analysis of trends; j. identifying root causes using individuals trained in investigation techniques; k. providing feedback at regular intervals and action-tracking mechanisms to ensure lessons learnt result in action to avoid repeating such events and/or to minimize their potential impact; l. identifying where security professionals may be required to coordinate with law enforcement.
		Element 12 – Facility Physical Requirements The Facility Physical Requirements element looks at how the organization addresses biorisk during periods when something new is introduced or the existing set-up is changed. Issues addressed include identifying the people who need to be involved and consulted, incorporating biorisk into planning, approaching commissioning in a structured way (including the role of suppliers), considering the physical characteristics of the materials used and carrying out any certification that may be needed. **Subelements** 12.1 Planning, Design and Verification 12.2 Commissioning and Decommissioning 12.3 Infrastructure and Operational Management		
	12	**FACILITY PHYSICAL REQUIREMENTS**		
	12.1	**Planning, Design and Verification**		

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CWA 4.4.4.8.1	12.1.1	A formal planning, design and redesign process is adopted for the facility, based on an assessment of risk associated with the materials to be used and activities undertaken.		A formal design process means a structured and documented approach, whereby the facility's needs are determined through risk assessment. Engineering and operational solutions will be incorporated that are consistent with the risk posed by the properties of the materials to be stored and handled in the facility and the nature of the work to be carried out.
CWA 4.4.4.8.1	12.1.2	The design process identifies and incorporates all relevant legislative requirements, together with information from recognized standards, guidelines (WHO *Laboratory biosafety manual*, *Third edition*, 2004), industry good practices and facility-specific risk assessments.		The design process should include identifying and reviewing relevant legislation and codes of practice (including building codes as well as those related to laboratory biosafety/laboratory biosecurity) and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and standards of acceptance to ensure performance. The process should be documented and transparent to provide assurance that it has been comprehensive and thorough.
CWA 4.4.4.8.1	12.1.3	The design process identifies and facilitates consultation with all relevant parties associated with the facility and its operation.		The design process should include identifying and consulting with individuals involved in the planning, construction, operation and maintenance of the facility. The following roles/individuals should be considered in terms of information requirements and consultation: a. scientific personnel and other end users; b. the biorisk management adviser and biorisk management committee; c. biosecurity and/or security personnel; d. designers (architects and engineers); e. constructors; f. maintenance engineers; g. material and equipment suppliers; h. commissioning agents;

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				i. certifiers; j. regulators; k. WHO; l. first responders; m. other relevant parties identified in risk assessments. If justified, and based on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specifications: a. are in line with accepted good practice; b. incorporate features capable of providing assurance regarding the control of poliovirus materials; c. integrate relevant legislative requirements, as well as standards and risk assessment findings, in the design.
CWA 4.4.4.8.1	12.1.4	All design features, construction techniques, materials and equipment selected are documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specifications.		
CWA 4.4.4.8.1	12.1.5	New construction and physical facility modifications are carried out according to an approved plan.		
	12.2	**Commissioning and Decommissioning**		
CWA 4.4.4.8.2	12.2.1	A formal process exists for: 1. the initial commissioning of new facilities; 2. the final decommissioning of existing facilities.		Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase during the first stage of science programme definition to ensure the expectations for the building are achievable. The commissioning plan should be developed in detail in parallel with the physical concept to ensure the expectations for the building are measurable. The commissioning plan should clearly identify all the steps from beginning to end, providing

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				examples and including the conditions of acceptance of each step as a prerequisite for proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after any temporary shutdown. The commissioning process should provide the benchmark for acceptable facility operation and the description of the programme to be put in place to maintain that level of performance. The decommissioning process should identify the decontamination procedures and security-related measures that must be in place for the facility's temporary or final shutdown. The decommissioning programme should describe not only the procedures, but also the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned facility can be re-entered.
	12.3	**Infrastructure and Operational Management**		
CWA 4.4.4.8	12.3.1	Facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management. The poliovirus facility incorporates features that are guided by assessments of the risk of poliovirus reintroduction in the community and includes the following provisions: a. Poliovirus facilities are located in countries with demonstrated high national immunization coverage (= DTP3 coverage).		

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		b. Poliovirus facilities are located in areas with closed sewage systems with secondary or greater treatment of effluents. c. Poliovirus facilities are either poliovirus dedicated or used on a campaign basis with documented effective decontamination procedures between periods of work with agents other than poliovirus. d. The containment perimeter is a defined working area sealable for gaseous decontamination and with sealed penetrations to prevent uncontrolled outward airflow. The containment perimeter is required irrespective of the choice of primary containment. e. The use of devices (e.g. BSCs) that are validated to maintain primary containment is required for all procedures using live poliovirus. Facilities using Class III BSCs will meet all physical aspects of this standard with deviation in procedures permitted during the BSC's normal operation (i.e. showering out is not required when Class III BSC is functioning properly). f. Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time, alarms, and associated operating procedures to ensure the building systems function effectively at all times. g. Controlled exit from the containment perimeter is via a walk-through exit shower. Showering is mandatory except for facilities employing fully functional Class III BSCs or similar isolators (in such facilities, showering out is required in the event of an uncontrolled breach of the primary containment equipment). h. Throughout the poliovirus type 2 containment period, a dose of IPV will be introduced, high global vaccine coverage will be maintained (population immunity is not expected to decline) and the use of monovalent oral polio vaccine type 2 (mOPV2) for outbreak response		

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		is considered. Where evidence of the satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, the controlled air system maintaining directional airflow will not require HEPA filtration on exhaust. i. Throughout the poliovirus type 2 containment period, a dose of IPV will be introduced, high global vaccine coverage will be maintained (population immunity is not expected to decline) and the use of mOPV2 for outbreak response is considered. Where evidence of the satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, decontamination of effluents is not required. j. The decontamination of all materials exiting the facility is achieved through a validated sterilization/decontamination procedure. Examples include: – a dedicated pass-through autoclave with a bioseal, interlocking doors to prevent opening the clean side prior to cycle completion, HEPA filtration of air discharge, cycle recording mechanisms and alarms; – a material airlock/decontamination chamber sealable for gaseous decontamination; – a dunk tank containing sufficient active compound to inactivate poliovirus. The poliovirus animal facility will incorporate features guided by risk assessments as described above and will meet all poliovirus containment criteria as described in this document, including: a. complying with containment criteria for animal facilities, consistent with the controls outlined in other sections of this document; b. specially training and supervising personnel responsible for inoculating, harvesting, sampling, performing animal autopsies, and for any other manipulations with poliovirus infected animals; c. requiring the use of devices (e.g. BSCs) that are validated to maintain primary containment for all animal manipulations with live poliovirus;		

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		d. housing infected animals separately; e. maintaining barriers to prevent infected animals from escaping; f. maintaining accurate records and accounting for all infected animals; g. meeting international criteria for laboratory animal care; h. using security procedures specific for facilities housing animals involved in biomedical research.		
		Element 13 – Equipment and Maintenance The Equipment and Maintenance element aims to ensure that biorisk is taken into consideration during the selection of all equipment that has implications for its control. Emphasis is placed on selection procedures, the maintenance of asset registers, control over where the equipment may be moved, and what it will be used for over its working life. Particular attention is also given to ensuring the equipment functions properly by following prescribed periodic and predictive maintenance, supported by adequate breakdown response. **Subelements** 13.1 Maintenance Management 13.2 Control of Equipment 13.3 Calibration 13.4 Certification 13.5 Validation		
	13	**EQUIPMENT AND MAINTENANCE**		
	13.1	**Maintenance Management**		
CWA 4.4.4.8.3	13.1.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are maintained in a manner consistent with the intent and requirements of the biorisk management programme.		The maintenance programme should apply to all aspects of the physical structure (including finishes and seals, where appropriate) and equipment therein. All materials used should be specified to ensure they can perform in line with

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				predetermined criteria. An appropriate maintenance plan will be addressed as part of that specification process. In planning and conducting maintenance activities, the organization should consider: a. adequately maintaining the facility's physical integrity and its fixtures and fittings; b. ensuring competent individuals perform the maintenance activities, and the risks associated with the work have been subjected to a risk assessment; c. ensuring adequate controls are in place to prevent workers from being exposed to poliovirus during their work; d. identifying and recording maintenance requirements during the construction of facilities or when equipment is purchased/acquired; e. creating and maintaining a maintenance register for all applicable equipment; f. identifying and conducting planned maintenance activities at an appropriate frequency; g. ensuring unplanned (breakdown) maintenance is adequately provided for so the facility's integrity is maintained at all times; h. determining and monitoring predictive maintenance requirements and associated indicators and monitors; i. ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement; j. establishing a pest control programme.
	13.2	**Control of Equipment**		

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CWA 4.4.4.8.3	13.2.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are controlled in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting equipment controls, the organization should consider: a. identifying equipment in line with work needs, which can be demonstrated as fit for purpose; b. controlling the purchase/acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel; c. controlling the entry and exit of equipment to and from the poliovirus facility, including decontamination requirements (e.g. air locks and decontamination); d. ensuring the asset register is regularly updated; e. ensuring stocks and supplies of equipment are sufficient.
	13.3	**Calibration**		
CWA 4.4.4.8.3	13.3.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are calibrated in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting calibration activities, the organization should consider: a. identifying and recording calibration requirements at the time of purchase/acquisition; b. identifying the standards/tests to use to ensure the equipment is correctly calibrated; c. establishing procedures to conduct calibrations on equipment used in live virus areas; d. creating a documented and up-to-date calibration register for all applicable equipment; e. ensuring calibration is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.4	**Certification**		
CWA 4.4.4.8.3	13.4.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact		In planning and conducting certification activities, the organization should consider:

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		on biorisk are certified in a manner consistent with the intent and requirements of the biorisk management programme.		a. identifying and recording certification requirements at the time of purchase/acquisition of equipment, including relevant and current standards against which to certify; b. ensuring competent and independent certifiers are used for the certification process; c. ensuring certification is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.5	**Validation**		
CWA 4.4.4.8.3	13.5.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are validated in a manner consistent with the intent and requirements of the biorisk management programme.		In planning and conducting validation activities, the organization should consider: a. identifying and recording validation requirements at the time of purchase/acquisition; b. identifying the standards/tests to use to ensure the equipment is correctly validated; c. creating a documented and up-to-date validation register for all applicable equipment; d. ensuring validation is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments; e. ensuring competent and independent validation mechanisms are used for the validation process. For physical security systems, the analogous concept is performance testing and evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed.
		Element 14 – Decontamination, Disinfection and Sterilization The Decontamination, Disinfection and Sterilization element examines the controls in place to ensure that appropriate disinfection, decontamination		

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		and sterilization routines manage the risk presented by the organisms and work activities undertaken. The element addresses general requirements for procedures, training and waste disposal as well as more specific issues, including the potential need for specialist laundering and issues specific to animal facilities. **Subelements** 14.1 Management of Biological Waste 14.2 Inactivation of Poliovirus Materials		
	14	**DECONTAMINATION, DISINFECTION AND STERILIZATION**		
	14.1	**Management of Biological Waste**		
CWA 4.4.4.5.3	14.1.1	The organization has established and maintains an appropriate waste management policy for poliovirus materials. No viable poliovirus will be released from the facility unless approved by the competent authority for transfer to another approved facility under controlled conditions. Potential routes whereby viable poliovirus could unintentionally exit the facility will be identified and adequate prevention measures put in place.		The organization should have a validated procedure for the inactivation of poliovirus waste products. The following elements should be considered for a waste management policy: a. ensure a programme is in place to minimize waste production; b. ensure effective waste audit trails are in place and documented; c. provide adequate facilities and procedures for the storage of waste (including short-term storage); d. ensure methods are available to effectively segregate and decontaminate mixed waste (e.g. infected animals that have received radioactive materials); e. ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transportation.
CWA 4.4.4.5.2	14.1.2	All contaminated or potentially contaminated waste items (including those that may result from an emergency) have been: 1. identified; 2. documented.		Sources of contamination that should be considered include: a. personnel; b. clothing and PPE; c. glassware; d. equipment;

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				e. cultures and associated materials; f. spill clean-up materials and equipment; g. possibly infectious microorganisms, toxins and contaminated materials; h. paper and plastic waste; i. needles, syringes and sharps; j. waste water, including that from sinks and showers; k. air; l. filters and air handling systems; m. discarded equipment used in the facility; n. animals exposed to laboratory poliovirus; o. animal carcasses and bedding; p. facilities. All potential waste streams and other sources of contamination should be identified and documented. For each of these sources, procedures should be put in place to validate the decontamination regime, and records will demonstrate that no contaminated persons/materials leave the facility and that inactivation measures have been implemented effectively.
CWA 4.4.4.5.2	14.1.3	Efficient procedures are in place to devise effective decontamination and other appropriate treatments.		Contaminated personnel may include core personnel working within the facility, contractors and emergency response personnel. Cultures and associated materials may be a source of contaminated supernatants, aspirates and culture media. Infected biological materials may also include infectious human, animal or plant specimens. In some instances, contaminated dedicated equipment, such as fire-fighter apparel or ambulance tools, may need to be held on-site if they cannot be effectively decontaminated.

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				Risk assessment should be an integral part of the process to identify and develop effective decontamination regimes.
	14.2	**Inactivation of Poliovirus Materials**		
CWA 4.4.4.5.2	14.2.1	Procedures are established and maintained to ensure appropriate disinfection and decontamination methods are chosen and implemented effectively. Procedures are established, validated and maintained for the effective poliovirus decontamination of the facility. Inactivation of poliovirus. Procedures are established and maintained to ensure the complete inactivation of all poliovirus from all materials and solid waste streams leaving the containment perimeter, including: 1. Heat sterilization (autoclaving) is the preferred method to inactivate polioviruses. 2. SOPs are available to address both routine and non-routine activities (e.g. daily routines vs major spills). 3. SOPs are developed to respond to the failure of the decontamination procedure or equipment. 4. SOPs are validated and shown to be effective against poliovirus prior to their use. 5. All materials leaving the containment perimeter, including clothing and liquid/solid waste, are heat sterilized or subject to chemical treatment of proven effectiveness prior to their removal. 6. All materials leaving the containment perimeter are accompanied by documentation on their decontamination. 7. Resources are available to deal with emergencies, accidents and other incidents. 8. Any live poliovirus that may be removed from the facility will be taken		Whatever poliovirus materials are handled, a number of effective inactivation methods are likely to be available. The organization should ensure data are available to demonstrate that the methodology selected is capable of inactivating the poliovirus materials under the specific conditions encountered in the facility. Validation measures should consider such issues as: a. the nature of the material being treated (e.g. volume, presence of protein/other potentially inhibitory substances); b. contact times, material compatibility issues (e.g. interaction with stainless steel or rubber seals); c. potential health hazards associated with the disinfectant; d. the need to maintain the required level of active compound, including deterioration over time. In planning and conducting decontamination activities, the organization should consider: a. ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and such concentrations are maintained throughout the process, including conducting specific validation activities where necessary; b. providing adequate facilities and procedures for the storage of waste (including short-term storage); c. ensuring methods are available to effectively decontaminate mixed waste (e.g. infected animals that have received radioactive materials);

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		away in a dunk tank, decontamination chamber or other validated mechanism to ensure the disinfection of the exterior surfaces of any packaging materials used. 9. The facility inactivates all waste and potentially contaminated material before it is passed to contractors or other third parties for waste disposal.		d. ensuring , methods are available, where appropriate, to decontaminate sensitive equipment not suitable for autoclaving (e.g. computers); e. implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and the use of indicators in autoclaves); f. decontaminating protective clothing by appropriate means prior to leaving the facility; g. ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during the handling and transport of materials inside and outside the facility; h. implementing programmes to ensure the amount of contaminated waste is minimized.
		Element 15 – Transport Procedures The Transport Procedures element explores how an organization deals with issues associated with the internal and external transport of biological materials, and looks at the necessary roles and responsibilities, materials and equipment, as well as the need to work with specialist couriers and shipping agents. **Subelement** 15.1 Transport Procedures		
	15	**TRANSPORT PROCEDURES**		
	15.1	**Transport Procedures**		
CWA 4.4.4.9	15.1.1	Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials, both inside and outside the facility containment perimeter, are established and maintained in accordance with legal requirements for the transport of dangerous goods.		In planning and conducting transport activities, the organization should consider: a. ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines;

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				b. ensuring the internal transport of poliovirus (within the facility, but outside the containment perimeter) meets the equivalent biosafety and biosecurity standards required for external transport outside the facility; c. ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transport process; d. selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely; e. determining whether a request for poliovirus materials is being made by an approved facility for a legitimate reason, and equivalent controls are applied to the importation of material to the facility; f. identifying the need for formal documented transfer forms signed by the responsible management representative authorizing the movement of the materials; g. using document controls that allow the traceability of material movements; h. identifying and implementing adequate and proportionate emergency response and contingency plans associated with the transport of poliovirus materials, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off.
		Element 16 – Security The Security element examines how an organization manages security with regard to biorisk. The element looks not only at some of the more obvious issues, such as access control, but also at the need for information security and support from external agencies.		

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		Subelements 16.1 Physical Security 16.2 Information Security 16.3 Personnel Control 16.4 Personal Security 16.5 Contractors, Visitors and Suppliers		
	16	**SECURITY**		
	16.1	**Physical Security**		
CWA 4.4.4.8.4	16.1.1	Controls are implemented and maintained for the physical security of cultures, specimens, samples and potentially contaminated materials or waste, determined as part of the risk assessment process.		Measures should be put in place to minimize the potential for release or removal of poliovirus materials from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms. In planning and conducting security risk assessments, the organization should consider: a. the theft or diversion of poliovirus materials or related equipment, documents or data; b. sabotage, including vandalism and tampering; c. break-in and intrusion; d. labour issues and disputes; e. kidnapping and extortion; f. weather-related emergencies (e.g. earthquake, tsunami, flood, tornado, hurricane); g. workplace violence; h. the failure of utilities; i. picketing, occupation and barricade; j. the screening and isolation of suspect packages; k. acts of terrorism;

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				l. civil unrest or war; m. cyberthreats. Care should be taken to coordinate biosecurity and biosafety measures to manage and minimize conflicting priorities. Security breaches should be reported, recorded and investigated as accidents and incidents. Procedures for the physical security of poliovirus materials, including cultures, specimens, samples and potentially contaminated materials, should be implemented and maintained, ensuring: a. the containment facility is located on a secure site with perimeter control to discourage unauthorized access; b. the containment facility is located away from uncontrolled traffic flows and its entrance is via a locked door with two-factor access control measures (e.g. requiring an electronic pass and personal access code); c. a second person within the containment perimeter or in close proximity is aware during poliovirus manipulations of the work being conducted and is available for contact if needed; d. the facility's perimeter is subject to constant monitoring (e.g. through the use of alarms, security personnel and closed-circuit television); e. measures are implemented to identify and record all personnel in the facility at any point in time; f. anti-intrusion alarms and sensors are installed, including interfaces with police and other security services;

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				g. panic buttons and "silent" emergency alert measures are implemented (e.g. key codes to alert security in the event of a hostage situation).
	16.2	**Information Security**		
CWA 4.4.4.8.5	16.2.1	A policy and procedure are in place to identify sensitive information.		The information generated by a laboratory can be as valuable and/or dangerous as the poliovirus materials stored at the facility. Adequate measures to prevent the unauthorized release of such information are critical. Procedures addressing information security should consider: a. the secure storage of all sensitive written records and data (e.g. virus inventories, security plans, security inspection reports, design drawings, maintenance plans, human resource information including worker contact details), including electronic records and electronic signatures; b. computer security, including robust Internet firewalls and encryption protocols; c. strict policies regarding PCs, laptop computers, storage media and cameras, among others, entering or leaving the facility; d. the thorough destruction of paper files to be discarded, and complete erasure of unwanted electronic files.
CWA 4.4.4.8.5	16.2.2	A review and approval process is used to control access to sensitive information.		
	16.3	**Personnel Control**		
CWA 4.4.4.7.1	16.3.1	A personnel reliability policy is defined and implemented.		The nature and extent of the measures required for the personnel reliability assessment should be determined as part of the risk assessment process. The organization will ensure that

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				access to poliovirus containment areas is limited to members of personnel who have been screened for subversive behaviours/ associations or criminal records or to those accompanied at all times by authorized individuals (as in the case of visitors, contractors, etc.). The screening includes: a. association with organizations that could present a threat to the facility's integrity; b. medical conditions that could lead to unstable/undesirable behaviour; c. assurance that individuals do not work under the influence of drugs or alcohol.
CWA 4.4.4.7.1	16.3.2	The organization ensures that individuals' access to facilities or work is controlled, according to the policy.		Where lawful and appropriate as determined by risk assessments, screening may include such checks as identity and immigration status, membership in organizations hostile to biological research, criminal records and financial probity.
	16.4	**Personal Security**		
CWA 4.4.4.10	16.4.1	A policy is in place to provide personal security support services to staff members, including, where appropriate, personal security awareness training. Documented security drills and exercises are conducted and prepare personnel and learn from any deficiencies.		Personal security is concerned with staff security during off-duty hours while away from the facility. During these times, staff members are vulnerable because of their function or position.
	16.5	**Contractors, Visitors and Suppliers**		
CWA 4.4.4.7.2	16.5.1	The organization ensures that suppliers, contractors, visitors and subcontractors adhere to the established management systems' requirements and do not compromise the facility's biorisk management.		

ANNEX 4

WHO verification that certified poliovirus-essential facilities comply with GAPIII

Purpose of compliance verifications

WHO will verify that nationally certified poliovirus-essential facilities[21] comply with 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).*

Verification results will inform the decision of the national authority to revoke or maintain certification against GAPIII.

Verification reports, their findings and observations will be submitted to the respective Regional Certification Commission (RCC) for evaluation and decision whether the poliovirus-essential facilities in the concerned country comply with the WHO Global Action Plan (GAPIII).

WHO verification process

- Request for WHO verification. Countries or concerned facilities may apply through their national authorities for WHO verification of poliovirus-essential facilities, certified by the MoH or another designated national authority, and confirmation of whether the facility meets all biorisk management criteria consistent with Annexes 2 and 3.

  Applications are submitted through the WHO regional office to WHO. Separate applications must be submitted for each facility.

- Compliance with WHA resolutions (14). Verifications will cover the management of laboratory biorisk, addressing biosafety and laboratory biosecurity, but not the poliovirus-essential facilities' programme of work.

- Composition of the verification team. The composition of the verification team will be decided by WHO on a case-by-case basis, and will include expertise in a number of areas relevant to GAPIII. The competence, role and reporting lines of individual team members will be described before the verification visit and will be detailed in the invitation letter sent to each team member.

  Verification team members must not be employees of the facility or its parent organization and must have no financial or ethical conflict of interest. Signed Declarations of Interest must be on file in WHO.

  Team members will be permitted to enter all areas related to the management and operation of the facility and have access to all relevant programmatic information, protocols and records. Team members will respect and adhere to facility biorisk management policies and procedures, including, when necessary, showering out and wearing protective clothing.

[21] Laboratories or polio vaccine production facilities.

- Compliance with GAPIII. WHO will use GAPIII as the basis for the verifications and will ask assessed certified poliovirus-essential facilities to demonstrate compliance with GAPIII requirements. Achieving compliance with GAPIII will allow poliovirus-essential facilities to demonstrate that acceptable levels of safety/security have been reached and will be maintained.

  When necessary, priority will be given to the verification of GAPIII compliance of WPV-holding facilities.

  WHO does not "certify" poliovirus-essential facilities against GAPIII.

- Preparation of verification visits. Relevant documents, including regulatory requirements, will be identified and requested from the facility. Sections that may need translation before the verification visit will be highlighted, allowing sufficient time for translations to be completed and reviewed by team members. Advance copies of biosafety manuals, standard operating procedures (SOPs) and other relevant information may also be requested.

- Agenda of verification visits. The agenda for individual visits will be developed and finalized by WHO, in consultation with the concerned facility.

  The timing and duration of the verification visit, and whether the facility should be visited while work with poliovirus is ongoing or when the facility has been decontaminated and is not being used for work with poliovirus, will be clarified with the concerned facility before any planned verification visit.

- Reporting routines, timelines and format. The verification team will make a presentation of findings on the final day of the visit and issue a draft written report later, for review by the concerned facility. WHO will conduct final clearance of the report, informing the national authority of its findings.

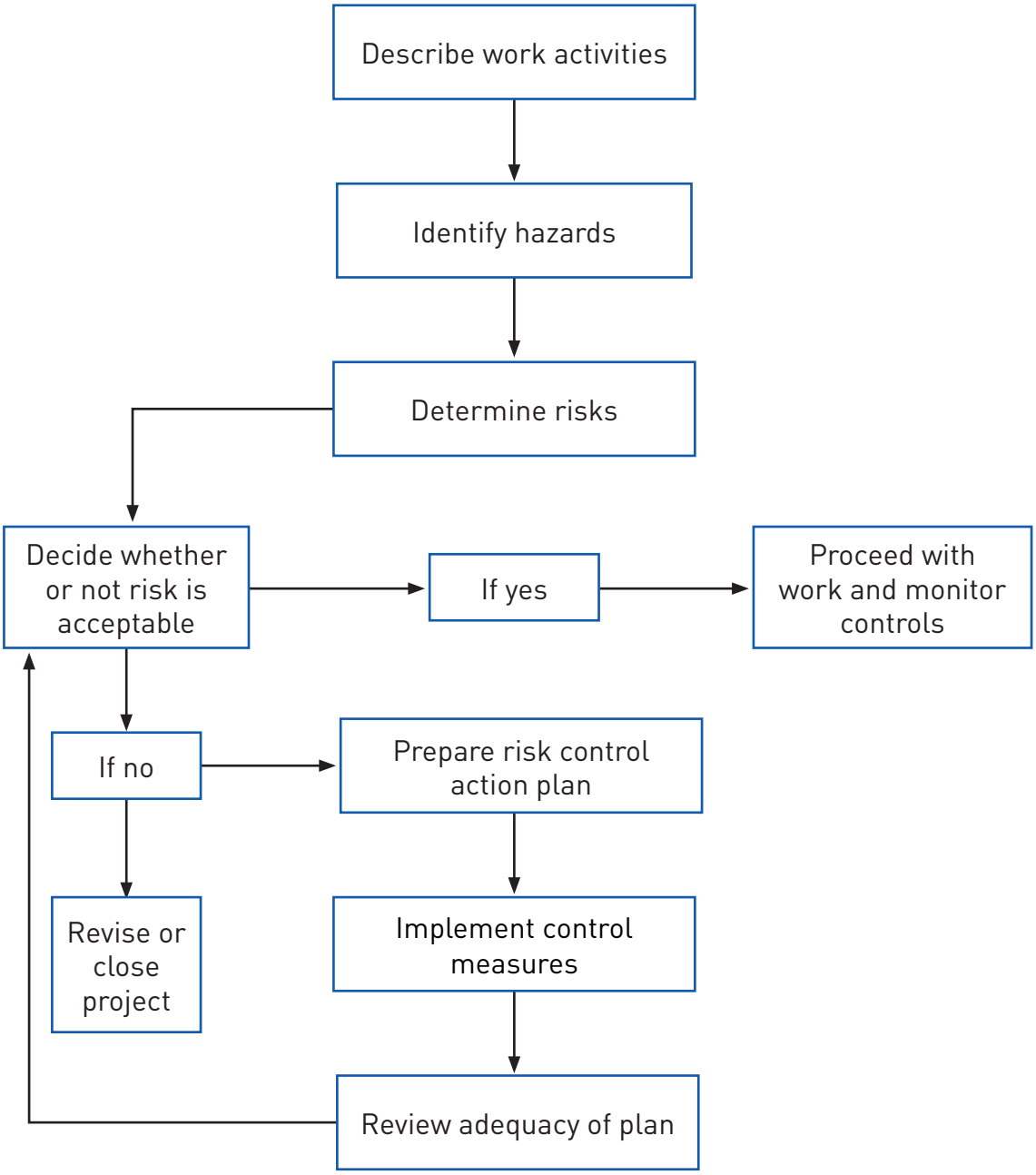
  In consultation with the national authority, the full final report will be submitted to the RCC.

- Response to findings necessitating corrective action. Identified non-compliances will be addressed within a timeframe agreed upon by the concerned parties (WHO, the concerned facility and the national authority) and will include follow-up reporting and, where necessary, additional visits, should the severity of the issue justify such measures.

ANNEX 5

Risk assessment strategy

Figure A5.1: Example of a risk assessment strategy (2)



ANNEX 6

Biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities

Introduction

A facility-associated poliovirus infection or release into the environment during the Endgame Strategy period and following eradication and cessation of oral polio vaccine (OPV) use will be a public health event of international proportions. The *Global Action Plan* addresses that risk by establishing a post-eradication/post-OPV cessation goal of not retaining poliovirus in poliovirus-non-essential facilities worldwide.

- As of Phase IIa, poliovirus-non-essential facilities (i.e. facilities that will not have a need to retain/store poliovirus infectious or potentially infectious materials) likely to investigate new WPV2, aVDPV2, cVDPV2 or iVDPV2 isolates, or new faecal and respiratory samples originating from recent OPV-using countries, are requested to:
  - implement safe and secure working practices based on the risk assessment and appropriate biorisk management systems;
  - not retain any WPV2 materials for long-term storage;
  - immediately destroy any newly isolated WPV2 materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

- As of Phase IIb, the poliovirus-non-essential facilities described above are requested to:
  - implement safe and secure working practices based on the risk assessment and appropriate biorisk management systems;
  - not retain any WPV2 or OPV2/Sabin2 materials for long-term storage;
  - immediately destroy any newly isolated type 2 poliovirus materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

- As of Phase IIIa, poliovirus-non-essential facilities (i.e. facilities that will not have a need to retain/store poliovirus infectious or potentially infectious materials) likely to investigate new WPV, aVDPV, cVDPV or iVDPV isolates, OPV2/Sabin2 materials or new faecal and respiratory samples originating from recent bOPV-using countries, are requested to:
  - implement safe and secure working practices based on the risk assessment and appropriate biorisk management systems;
  - not retain any WPV or OPV2/Sabin2 materials for long-term storage;
  - immediately destroy any newly isolated WPV or OPV2/Sabin2 materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

- As of Phase IIIb, the poliovirus-non-essential facilities described above are requested to:
  - implement safe and secure working practices based on the risk assessment and appropriate biorisk management systems;
  - not retain any WPV or OPV/Sabin materials for long-term storage;
  - immediately destroy any newly isolated poliovirus materials, or transfer them to a certified poliovirus-essential facility after notifying the MoH or another designated national authority and WHO.

The table below describes the biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories. This standard is based on CWA15793, *Laboratory biorisk management* (2). It consists of 16 elements and subelements based on the principles of a quality management system. It assumes that the organization is best placed to understand the risks associated with its work and can manage those risks in a number of ways acceptable to the national and international bodies responsible for facility oversight. This standard further assumes that poliovirus-essential facility personnel and management at all levels fully appreciate the enormity of the consequences of accidental or malicious poliovirus release in the post-eradication/post-OPV era and are prepared to demonstrate that the appropriate systems and controls are in place to manage those risks.

Poliovirus facility-associated risks

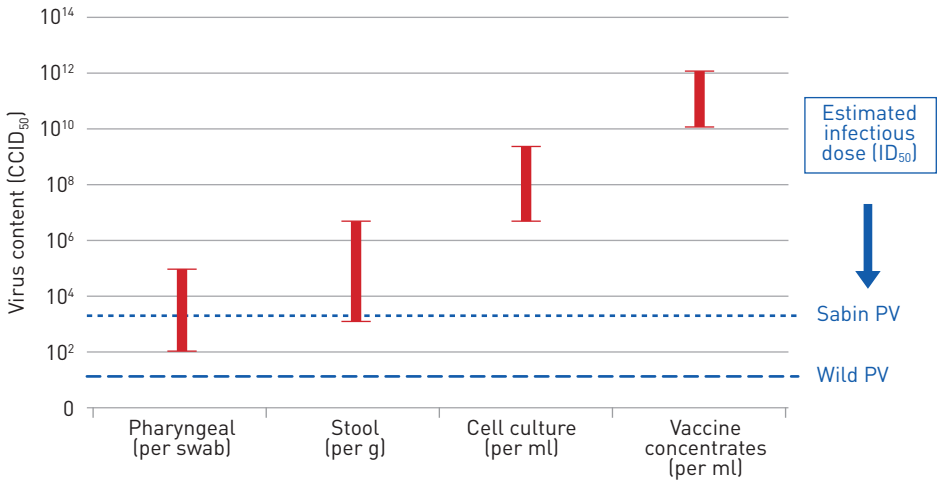
Polioviruses under moist conditions in clinical or environmental samples can survive indefinitely in the laboratory freezer (<-20 °C), for many months in the refrigerator and for weeks on the bench top at ambient temperatures (18). Infectivity is inactivated by dehydration, heat (>50 °C) or treatment with dilute solutions of formaldehyde or bleach at appropriate concentrations.

The most common routes of exposure to infectious agents in the facility environment are (1) ingestion; (2) inhalation; (3) injection; and (4) contaminated skin and mucous membranes. The infectious dose is a factor of virus virulence, the route of presentation and virus particles in sufficient number to overcome mechanical loss and natural and immune host defences. In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/g (Sabin) to $10^{4.3}$ $CCID_{50}$/g (wild) in stool samples, to10^{8} $CCID_{50}$/ml in cell culture harvests, and 10^{11} $CCID_{50}$/ml in concentrates in vaccine production facilities. Sabin strains are less pathogenic than wild and have lower secondary infection rates, but all three Sabin virus types have been linked to vaccine-derived poliovirus (VDPV) outbreaks.

Ingestion presents the highest risk for facility personnel. Immunization with OPV or inactivated polio vaccine (IPV) prevents disease, but neither fully inhibits silent poliovirus infection nor reinfection of the gut. Ingestion of poliovirus may result from any laboratory operation, activity or incident that leads to the transfer of infectious particles to the gastrointestinal tract. Estimated infectious doses (ID_{50}) by ingestion, based on studies with infants and children, are $\pm 10^1$ $CCID_{50}$ for wild polioviruses and $\pm 10^3$ $CCID_{50}$ for Sabin strains. Immunized adult laboratory workers are likely more resistant than immunologically naïve children, but resistance is dose related and may be overcome by ingesting sufficient poliovirus particles. Droplets created by sprays, spills and the splash of poliovirus cell cultures (10^8 $CCID_{50}$) and concentrates (10^{11} $CCID_{50}$) constitute the highest personnel exposure risks (Figure A6.1).

Inhalation, defined as exposure to small particle aerosols of <5 µm (droplet nuclei) deposited predominately in the lower respiratory tract, has been identified as a possible route of infection for poliovirus. The respiratory tract appears not to be a significant portal of entry. Unresolved, however, is whether small particle aerosols deposited in the lower respiratory tract may initiate alimentary tract infections through mucociliary transport to the pharyngeal region. Inhalation risks may be further reduced in facility environments maintained at low relative humidity (<50%). Antibodies acquired through immunization greatly reduce infection risks from injection or breaks in skin or mucous membranes.

Figure A6.1: Estimated poliovirus content and infectious dose[22]



[22] Estimated infectious doses (ID_{50}) are based on studies with infants and children. Immunized adult laboratory workers are likely much more resistant than immunologically naïve children. However, dose-related resistance may be overcome by ingesting sufficient poliovirus particles.

Community members may be exposed to infectious agents from the laboratory through (1) workers' contaminated skin or clothing or unrecognized infection; (2) the release of contaminated air; (3) contaminated effluents and waste water recovered from secondary sewage treatment plants; (4) the uncontrolled transport of infectious material; (5) solid waste transported to landfills; (6) contaminated equipment or materials removed from the facility; (7) the escape of infected animals; and (8) a theft or deliberate release of infectious agents from a facility. Exposure risks through routes 4-7 are low for poliovirus facilities that adhere to international regulations for the transport of infectious substances, those outlined in the *Good Laboratory Practice* handbook and the WHO guidelines on *Good Manufacturing Practice*, and likely low for the inhalation of contaminated air effluent where facilities maintain low relative humidity environments and exhaust air away from direct human exposure. Exposure risks through the ingestion of effluents range between high and low, depending on the poliovirus content of facility effluent, sewerage system size and integrity, and the potential for human consumption. Risks of community exposure are highest through facility personnel unknowingly contaminated or infected with poliovirus. IPV immunization of facility personnel may greatly reduce the risk of intra- and extra-household transmission.

Effective poliovirus risk management is achieved by the careful assessment of exposure risks, the implementation of risk-appropriate personnel protection measures, and the quality operation of a facility designed to minimize the risk of poliovirus contamination and dissemination to the community. The main risk is the infection of laboratory workers by ingestion. Airborne transmission is conceivable but not demonstrated and infection through parenteral exposure such as needlestick is unlikely in immunized individuals.

MANAGEMENT SYSTEM ELEMENTS

Biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
		Element 1 – Biorisk Management System The biorisk management system element examines the system and policy in place to manage laboratory biorisk. Effective management and organization are vital to the success of any activity, and management commitment and leadership lay the foundation upon which a solid biorisk management system is built. Management must have clear strategies and objectives from which roles and responsibilities are allocated, implemented and monitored. Without effective management commitment and appropriate organizational structures, all other initiatives aimed at managing risk will be ineffective. The way management thinks and acts has a major impact on performance. **Subelements** 1.1 Biorisk Management Policy 1.2 Objectives, Targets and Programme 1.3 Roles, Responsibilities and Authorities 1.4 Records, Documents and Data Control 1.5 Analysis of Data 1.6 Change Management 1.7 Consultation and Communication 1.8 Programme of Work 1.9 Work Planning and Capacity 1.10 Legal Requirements 1.11 Continual Improvement 1.12 Preventive Action 1.13 Control of Nonconformities 1.14 Inspection and Audit 1.15 Corrective Action 1.16 Contractors and Suppliers 1.17 Biorisk Management Review 1.18 Biorisk Management System	

[23] Clause numbers referenced from final CWA15793, 2011 published version.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
	1	**BIORISK MANAGEMENT SYSTEM**	
	1.1	**Biorisk Management Policy**	
CWA 4.2.1	1.1.1	Actions taken by top management demonstrating commitment to the policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity) include: 1. development; 2. authorization; 3. signing.	Biorisk management should be stated clearly as part of the organization's health, safety, security and environment (HSE) policies. Depending on the relevance of biorisk management to the organization, the biorisk management policy should complement the general HSE policies. As appropriate, the biorisk management policy may be integrated into the organization's HSE policies.
CWA 4.2.1	1.1.2	The policy clearly states: 1. the overall biorisk management objectives; 2. a commitment to improving biorisk management performance.	The policy should require that all projects/work areas be assessed for risks and a full assessment be prepared before approval is given to commence work.
CWA 4.2.1	1.1.3	The policy is appropriate to the nature and scale of the risk associated with the facility and associated activities.	
CWA 4.2.1	1.1.4	The policy commits to: 1. protecting staff, contractors, visitors, the community and the environment from biological agents and toxins that are stored or handled within the facility; 2. reducing the risk of the unintentional release of, or exposure to, biological agents and toxins; 3. reducing the risk of the unauthorized intentional release of hazardous biological materials to an acceptable level; 4. complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard; 5. ensuring that the need for effective biorisk management takes precedence over all non-"health and safety" operational requirements; 6. informing all employees and relevant third parties effectively and communicating individual obligations with regard to biorisk to these groups;	The policy includes the need to conduct risk assessments and implement the required control measures.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
		7. improving biorisk management performance continually.	
	1.2	**Objectives, Targets and Programme**	
CWA 4.3.3.1	1.2.1	Documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization are: 1. established; 2. implemented; 3. maintained.	
CWA 4.3.3.2	1.2.2	Management has established the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.	The controls can be monitored by regular audits, by utilizing corrective-action reporting processes where problems have been identified, by investigating incidents and accidents and improving controls and their implementation, and by ensuring adequate resources are provided to maintain the effectiveness of the controls. Note: Refer to Element 2 – Risk Assessment.
	1.3	**Roles, Responsibilities and Authorities**	
CWA 4.4.1.1	1.3.1	Top management takes ultimate responsibility for the organization's biorisk management system.	Top management includes officers (Director-General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and directors of the organization. Overall responsibility for managing biorisk rests with top management but tasks may be delegated through the organization, provided they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller organizations, one individual may hold more than one role described in this standard. It is important to define roles and responsibilities, have clear communication within the organization regarding actions that need to be taken, and establish who has the required authority.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
CWA 4.4.1.1	1.3.2	Top management ensures that roles, responsibilities and authority related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins.	In assigning roles and responsibilities, potential conflicts of interest should be considered. This standard has identified roles that need to be covered in the organization and has only used titles to illustrate these roles; these titles may not be the same as those used in specific organizations.
CWA 4.4.1.1	1.3.3	Top management demonstrates its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.	Resources include human resources and specialized skills, organizational infrastructure, technology and financial resources.
CWA 4.4.1.2	1.3.4	A senior manager has been designated with the operational responsibility to oversee the biorisk management system.	Senior managers are those with significant operational, budgetary and personnel authority at the departmental or higher level, and may include members of top management.
CWA 4.4.1.2	1.3.5	The senior manager's functions in managing biorisk include: 1. providing appropriate resources to ensure the adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; 2. reporting to top management on the performance of the biorisk management system and any need for improvement; 3. ensuring the promotion of the biorisk management system throughout the organization; 4. instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.	The senior management representative should be an individual with decision-making authority at a level whereby he/she can allocate resources and make decisions regarding the facility's biorisk management needs (including required resources to conduct risk assessments and other management and administrative activities) independently of the need to implement the programme of work.
CWA 4.4.1.3	1.3.6	A biorisk management committee has been constituted to act as an independent review group for biorisk issues associated with the facility.	The biorisk management committee is often recognized as the institutional biosafety committee. Its role may be either a dedicated function or one that is addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management adviser(s), the security manager and the occupational health

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			professional. Others, such as the facility manager and/or worker and community representatives, may be included depending on the nature of the agenda or work.
CWA 4.4.1.3	1.3.7	The biorisk management committee reports to senior management and: 1. has documented terms of reference; 2. includes a representative cross section of expertise, appropriate to the nature and scale of the activities undertaken; 3. ensures issues addressed are formally recorded, and actions are allocated, tracked and closed out effectively; 4. is chaired by a senior individual; 5. meets at a defined and appropriate frequency, and when otherwise required.	The committee's functions should include: a. contributing to the development of institutional biorisk policies and codes of practice; b. approving proposals for new work or significant modifications to the potential risk associated with existing activities; c. reviewing and approving protocols and risk assessments for work involving biological agents and toxins; d. reviewing information related to significant accidents or incidents, data trends, associated local or organizational actions and communication needs. The list of roles for the biorisk management committee is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.4	1.3.8	One or more competent individuals are designated to provide advice and guidance on biorisk management issues.	The competent individual providing advice and guidance on biorisk management is often recognized as a biological safety officer or biological safety adviser. This function should normally be regarded as an advisory position and not one directly responsible for managing biorisk, as that rests with those conducting and managing the work within the organization (e.g. the scientific director, principal investigator, department head, laboratory manager, group leader). The role and knowledge of the biorisk adviser are important to develop, implement, maintain and continually improve a biosafety and biosecurity programme based on a management system. The adviser should be competent to perform the role and be allocated sufficient time and other resources to do the job effectively.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
CWA 4.4.1.4	1.3.9	The biorisk management adviser's role is independent of the functions of those responsible for implementing the programme of work.	In the execution of their biorisk management duties, advisers should be independent from those responsible for implementing the programme of work and have direct access to the top management representative when necessary.
CWA 4.4.1.4	1.3.10	The biorisk management adviser: 1. reports directly to the responsible senior manager; 2. has delegated authority to stop work in the event that it is considered necessary to do so.	The biorisk management adviser's functions should include: a. verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed; b. advising or participating in the reporting, investigation and follow-up of accidents/incidents and, where appropriate, referring these to management and/or the biorisk management committee; c. ensuring relevant and up-to-date information and advice on biorisk management are made available to scientific and other personnel as necessary; d. advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security); e. contributing to the development and/or delivery of biorisk training activities; f. ensuring all relevant activities are performed in compliance with biorisk regulations, and the required biorisk authorizations for work are in place. The list of roles for the biorisk management adviser is not exhaustive but includes some of the main areas that should be addressed.
CWA 4.4.1.5	1.3.11	One or more individuals with responsibility for the scientific programme within the facility have been designated with responsibilities relevant to biorisk management.	The scientific manager is responsible for managing the scientific programme within the facility on a day-to-day basis, and for implementing and monitoring biorisk controls in association with other facility personnel (e.g. adhering to

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			policies and procedures, monitoring staff performance and participation in inspections and audits). The individual would normally have an in-depth knowledge of the work programme and the facility, would be in a supervisory/management position and may be referred to as Head of Department, Principal Investigator, Laboratory Supervisor/Manager or Group Leader. Competence is required in technical/scientific aspects of the biological agents and toxins being used and in their control, and in the management of the facility, its personnel and systems. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.5	1.3.12	The scientific management functions include: 1. ensuring all work is conducted according to established policies and guidelines described in this standard; 2. supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; 3. planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; 4. ensuring required authorizations for work are in place; 5. ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and the required control measures are in place; 6. ensuring all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).	
CWA 4.4.1.6	1.3.13	The organization has access to appropriate occupational health expertise.	The occupational health professional would normally be a medical doctor or occupational health nurse with an understanding of the biological agents and toxins handled within the facility.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			The role should include providing input into risk assessment from a worker's health perspective, advising on first aid/ emergency treatment measures and follow-up, liaising with external health-care providers, and coordinating medical examinations, surveillance and vaccination programmes. The occupational health professional's roles and responsibilities should be determined in light of requirements set out in this standard.
CWA 4.4.1.6	1.3.14	The organization has established an occupational health programme commensurate with the facility's activities and risks.	
CWA 4.4.1.7	1.3.15	One or more facility managers have been appointed with responsibilities relevant to facilities and equipment, determined according to requirements set out in this polio biorisk management standard.	The facility manager would normally be an engineer or a person with an in-depth knowledge of laboratory facilities, containment equipment and buildings. The role should include providing input into risk assessment from a facility perspective, coordinating building and maintenance work, and liaising with contractors. The roles and responsibilities of the facility management personnel should be determined in light of requirements set out in this standard. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined to avoid any omissions and ensure consistency.
CWA 4.4.1.8	1.3.16	A security manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.	The security manager would normally have an in-depth knowledge of laboratory and facility security, should liaise with other personnel (e.g. the biorisk management adviser) and implement effective and proportionate laboratory biosecurity measures, based on the biological risk. The role should include providing input into risk assessment and management from a security perspective. The security personnel's roles and responsibilities should be determined in light of requirements set out in this standard.

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
CWA 4.4.1.9	1.3.17	In laboratories where animals are kept, an animal-care manager has been designated with responsibilities conforming to requirements set out in this polio biorisk management standard.	The animal-care manager would normally have an in-depth knowledge of animal handling, and zoonotic and animal diseases. The animal-care manager should liaise with other personnel (e.g. biorisk management adviser, occupational health professional) to implement effective and proportionate laboratory biosafety and biosecurity measures. A qualified veterinarian should be available for additional advice. The role should include providing input into risk assessment and management from an animal-care perspective.
	1.4	**Records, Documents and Data Control**	
CWA 4.5.2	1.4.1	Records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this polio biorisk management standard.	Where appropriate, documents should be identified and controlled based on the nature of the work and need for record-keeping.
CWA 4.5.2	1.4.2	Records, documents and data are handled in such a way that they remain legible, readily identifiable and retrievable.	Controlled documents may include: a. risk assessments, standard operating procedures (SOPs) and safety manuals; b. job hazard analyses and charts of authority; c. design records and commissioning/test plans, maintenance plans and records, and all associated data; d. audit and inspection checklists; e. laboratory biosecurity manuals and risk assessments, authorizations and other security documents; f. training records; g. containment equipment certifications. The list of controlled documents is not exhaustive but includes some of the main areas that should be formally recorded and subject to document control. Data should be construed as documents in this context. A procedure should be established

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			to define the controls needed for the identification, storage, protection, retrieval, retention period and disposal of records. A procedure should be established to define the controls needed for the approval of documents prior to their issue or public release, to ensure sensitive information such as the specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls needed for the review, update and reapproval of documents, and for the control of change and revision process.
	1.5	**Analysis of Data**	
CWA 4.5.1	1.5.1	Appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.	The analysis should include data generated as a result of monitoring, measurement, audits and analysis, and from other sources. Such analyses should be conducted at least annually, and more often if justified by the risks and scope of operations. The results of the analysis should be applied in the management review.
	1.6	**Change Management**	
CWA 4.4.4.4	1.6.1	All changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.	These changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include an evaluation of the effect of the changes on the risk assessment. Examples of changes that should be subject to the change management process include: a. modifications to buildings and equipment or their operation, which could or would have an effect on biorisk; b. introduction of altered staffing arrangements (such as the temporary presence of on-site contractors or students, temporary reassignments of personnel);

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			c. changes to the programme of work, including alterations to workflow or volume, which could or would have an effect on biorisk; d. alterations to SOPs, including significant changes in materials or reagents; e. modifications to entry/exit protocols; f. modifications to personnel policies and visitor protocols; g. modifications to disinfection, decontamination and other waste management methodologies; h. changes associated with the provision and use of personal protective equipment (PPE).
	1.7	**Consultation and Communication**	
CWA 4.4.4.3	1.7.1	Relevant biorisk information related to an organization's activities is communicated to and from employees and other relevant parties.	The organization should implement mechanisms to ensure relevant and current information that can potentially affect workers and others is defined and delivered effectively at appropriate intervals. This could entail regular team meetings and briefings in the workplace, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others, including: a. local, national and international governmental organizations; b. relevant regulatory agencies; c. certifiers; d. emergency services and health-care providers; e. contractors and suppliers (e.g. cleaners, maintenance providers, security personnel); f. local community representatives (e.g. through a community liaison committee). Systems should be put in place to identify existing or emerging technologies or other relevant information related to the

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
			containment of the biological agents and toxins being handled or stored. This information should be shared with relevant staff through appropriate media, including the circulation of appropriate signage, documents and team briefings, and the maintenance of reference libraries and other sources of information.
CWA 4.4.3	1.7.2	Employee involvement and consultation arrangements are documented.	
CWA 4.4.3	1.7.3	Personnel have access to adequate and up-to-date information about the organization's biorisks.	
	1.8	**Programme of Work**	
CWA 4.4.4.3	1.8.1	The programme of work for the facility is defined, documented and reviewed.	The programme should include the nature of the activities authorized to be conducted in the facility and their definitions (e.g. diagnostics, research, small scale/large scale). All activities associated with the work programme should be specified and supported by formal SOPs approved in line with the requirements for controlled documents, as defined by this standard. Any changes to the programme of work should be subject to a formal change management process.
CWA 4.4.4.3	1.8.2	Criteria are established for work that requires prior approval.	
	1.9	**Work Planning and Capacity**	
CWA 4.4.4.3	1.9.1	Sufficient resource capacity and capability are available to manage workflow, whether planned or unplanned.	The resources needed to implement and maintain the biorisk management system and continually improve its effectiveness should be determined and provided.
	1.10	**Legal Requirements**	
CWA 4.3.2	1.10.1	The organization ensures that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national/federal, regional/state, provincial, city and local	The organization should adopt measures to identify the facility's legal and other requirements related to the biological agents and toxins to be held and used, but also to other regulations

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		regulations with which the organization must comply.	including, for example, worker protection and rights, environmental impact, and general health and safety (e.g. fire, electrical). Monitoring for new and upcoming requirements, as well as those that already exist, is needed. This information
	1.11	**Continual Improvement**	
CWA 4.1.2	1.11.1	The organization continually improves the effectiveness of the biorisk management system through: • the policy; • its objectives; • the self-audit programme; • audit results; • the analysis of data; • the risk assessment; • corrective and preventive actions; • the management review.	The organization should strive to continue developing and refining the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved by setting objectives and giving targets to those working within the facility and by monitoring progress to ensure the objectives are achieved.
	1.12	**Preventive Action**	
CWA 4.5.4.4	1.12.1	Action is taken to identify and eliminate the causes of potential nonconformities to prevent their occurrence.	A procedure should be established to define requirements for: a. determining the potential nonconformities and their causes; b. evaluating the need for action to prevent the occurrence of nonconformities; c. determining and implementing the action needed; d. recording the results of action taken; e. reviewing the preventive actions taken.
CWA 4.5.4.4	1.12.2	Preventive actions are appropriate to the effects of the potential nonconformities.	
	1.13	**Control of Nonconformities**	
CWA 4.5.4.2	1.13.1	Situations that do not conform to the requirements of this polio biorisk management standard are identified and controlled to prevent undesirable consequences.	The controls and related responsibilities and authorities needed to deal with nonconforming situations should be defined in a procedure.

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CWA 4.5.4.2	1.13.2	Records are maintained of the nature of the nonconformity and any subsequent action taken.	
	1.14	**Inspection and Audit**	
CWA 4.5.5	1.14.1	An inspection and audit programme is conducted that is appropriate to the risk associated with the facility.	Inspections may be frequent checks of specific areas, conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels/concentrations, air exchange rates/ maintenance of directional air flow), or may be more extensive but less frequent inspections of laboratories, facilities or other operations. Random, unannounced inspections and inventory audits can help ensure compliance at all times and not just in time for scheduled inspections. Audits should be performed by competent individuals unaffiliated with the audited activity. Records of inspection/audit findings should be maintained, including action taken to close out any nonconformities or pursue improvement opportunities.
CWA 4.5.5	1.14.2	Inspections and audits are conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and the requirements of this polio biorisk management standard, and if it is effectively implemented and maintained.	
CWA 4.5.5	1.14.3	Management responsible for the area being inspected/audited ensures that any actions are taken without undue delay to eliminate detected nonconformities and their causes.	
CWA 4.5.5	1.14.4	Follow-up activities include: 1. verification of the actions taken; 2. reporting of the verification results.	
	1.15	**Corrective Action**	
CWA 4.5.4.3	1.15.1	To prevent the recurrence of any nonconformities, action is taken to eliminate their causes using the requirements of the polio biorisk	A procedure should be established to define requirements for: a. reviewing the nonconformities;

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		management standard for the safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories.	b. determining the cause of nonconformities; c. evaluating the need for action to ensure nonconformities do not recur; d. determining and implementing the action needed; e. recording the results of action taken; f. reviewing the corrective actions taken.
CWA 4.5.4.3	1.15.2	Corrective actions are appropriate to the effects of the nonconformities encountered.	
	1.16	**Contractors and Suppliers**	
CWA 4.4.4.8.6	1.16.1	Purchases (including services) conform to specified requirements.	
CWA 4.4.4.8.6	1.16.2	Controls on purchases (including services) are applied depending on the potential impact on the biorisk involved.	
CWA 4.4.4.8.6	1.16.3	Suppliers are evaluated and selected based on their ability to provide products/services that meet the requirements of this polio biorisk management standard.	While not all suppliers will provide products/services that may have an impact on biorisk, many may. Suppliers that should be considered include, but are not limited to, those that provide: a. cleaning services; b. laboratory equipment; c. waste management or disposal services; d. information technology support services; e. equipment and facility maintenance services; f. security services.
CWA 4.4.4.8.6	1.16.4	Criteria for selection, evaluation and re-evaluation are established.	
CWA 4.4.4.8.6	1.16.5	Records are maintained of evaluation results and any necessary actions arising from the evaluation.	
	1.17	**Biorisk Management Review**	
CWA 4.6.1	1.17.1	Top management reviews the organization's biorisk management system	The management review should be conducted regularly, at a

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		at planned intervals to ensure its continuing suitability, adequacy and effectiveness.	frequency determined by the needs of the organization, but at least annually.
CWA 4.6.1	1.17.2	The review includes: 1. assessing opportunities for improvement; 2. determining the need for changes to the system, procedures, policies and objectives.	Review input should include information on: a. the results of audits; b. compliance with SOPs and work instructions; c. the status of risk assessment activities; d. the status of preventive and corrective actions; e. follow-up actions from previous management reviews; f. changes that could affect the system; g. recommendations for improvement; h. the results of accident/incident investigations.
CWA 4.6.1	1.17.3	Records are maintained from the management review.	The review's output should include decisions and actions related to: a. improvement of the biorisk management system's effectiveness; b. improvement related to the requirements and risk assessments; c. resource needs.
	1.18	**Biorisk Management System**	
CWA 4.1.1	1.18.1	The organization has established, documented, implemented and maintains a biorisk management system according to the requirements of this polio biorisk management standard.	
		Element 2 – Risk Assessment The Risk Assessment element looks at how organizations define risk and implement effective mechanisms to identify, assess and manage those risks. Areas addressed include how to ensure consistency and transparency in assessing risk across the organization, without placing an unnecessary burden on specialists and support staff. This element is regarded as a foundation upon which the others must be based. **Subelements** 2.1 Process, Methodologies and Procedures	

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		2.2 Assessment Timing and Scope 2.3 Roles and Responsibilities 2.4 Hazard Identification 2.5 Risk Assessment 2.6 Risk Control	
	2	**RISK ASSESSMENT**	
	2.1	**Process, Methodologies and Procedures**	
CWA 4.3.1.1	2.1.1	The organization ensures that a risk assessment system is established, implemented and maintained according to this polio biorisk management standard.	
CWA 4.3.1.1	2.1.2	The risk management system's performance is reported to senior management for review and as a basis for improvement.	
CWA 4.4.4	2.1.3	The organization has identified those operations and activities associated with possible biological risk and where control measures are to be applied.	
CWA 4.4.4	2.1.4	Activities associated with possible biological risk, including maintenance, are carried out under specified conditions.	
	2.2	**Assessment Timing and Scope**	
CWA 4.3.1.2	2.2.1	The approach to risk assessment is defined according to its scope, nature and timing so it is proactive rather than reactive.	The following should trigger either a new risk assessment or the review of an existing one: a. commencement of new work or changes to the programme of work, including the introduction of new biological agents or alterations to workflow or volume; b. new construction/modifications to laboratories, plants and equipment or their operation; c. introduction of altered and unplanned staffing arrangements, including those concerning contractors, visitors and other non-core personnel;

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			d. significant alterations to SOPs or working practices (e.g. disinfection/waste management methodologies, PPE provision, usage entry, exit protocols); e. unexpected events that may be relevant to the management of biorisks; f. actual or potential nonconformity with internal/external rules and regulations (e.g. the introduction of new legislation or major accident exposure); g. consideration of emergency response and contingency planning requirements; h. the existing management system review process (e.g. annually or at another appropriate and predetermined frequency). Many defined methodologies and approaches are available to conduct hazard identification, risk assessment and control; the approach taken will vary depending on the nature of the situation and the level of detail required. One framework that organizations may consider adopting is outlined in Figure 1 of CWA15793, 2011 (GAPIII, Annex 5).
	2.3	**Roles and Responsibilities**	
CWA 4.3.1.1	2.3.1	Resource requirements have been identified and adequate resources provided, including assigning trained personnel to management, work performance and verification activities, including internal review.	The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need the organizational freedom and authority to: a. initiate action to prevent or reduce the adverse effects of risk; b. control the further treatment of risks until the level of risk becomes acceptable; c. identify and record any problems related to managing risks; d. initiate, recommend or provide solutions through designated channels;

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			e. communicate and consult internally and externally as appropriate.
	2.4	**Hazard Identification**	
CWA 4.3.1.3	2.4.1	The hazards associated with proposed work are: 1. identified; 2. documented.	The first stage in the risk management process is to identify all hazards relevant to biorisk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and risk management. A hazard may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting) or a material (in this case, the principal hazard is most likely to be a poliovirus, but others include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is its potential to cause harm, regardless of how likely such an occurrence might be. Biological hazards should be identified and assessed in relation to their potential damage to humans, animals and the environment. Where hazardous materials are classified into hazard or risk groups based on international and/or foreign country classification schemes, local diverging needs and constraints should be considered. A hazard identification exercise should use information that includes: a. group experience and knowledge; b. external or specialized expertise not found in the facility; c. results of previous assessments; d. surveys of previous accidents/incidents; e. hazardous materials data; f. information on hazardous organisms; g. guidelines and codes of practice;

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			h. facility drawings; i. SOPs, manuals, etc.; j. process maps. Defined methodologies and approaches are available to conduct hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and its activities. Hazard identification should be appropriate in nature and structure, and recorded to a level whereby others can review the process.
	2.5	**Risk Assessment**	
CWA 4.3.1.4	2.5.1	Suitable methodologies for assessing and recording risks are: 1. identified; 2. implemented; 3. maintained. Risk assessments are documented.	The risk assessment should categorize risks to identify those that need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels, should be defined and used in the assessment. Such a classification can be achieved, for example, by using a risk matrix that identifies likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate. Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. In conducting the assessment, due consideration should be given to the inherent risk from polioviruses (e.g. from risk grouping descriptions, material safety data sheets). After defining and implementing control measures, the risks should be reviewed to decide whether the remaining risk is acceptable or additional controls need to be identified and implemented.
	2.6	**Risk Control**	

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CWA 4.3.1.5.	2.6.1	Suitable methodologies for allocating actions that result from risk assessments, including timelines, responsible persons and associated reporting and approval mechanisms, are: 1. identified; 2. implemented; 3. maintained.	The risk management approach should have a control plan that includes: a. who is responsible and accountable for implementing the plan; b. what resources are to be used (e.g. people, budget); c. a timetable for implementation; d. details of the mechanism and frequency of reviewing compliance with the plan. Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls or the reliance on PPE.
		Element 3 – Pathogen and Toxin Inventory and Information The Pathogen and Toxin Inventory and Information element examines the systems in place to identify, record and review the organisms stored, received and transported from a facility. The level of detail and nature of the system depends on the pathogens being held, and ranges in complexity from simple lists to secure databases. This element also examines the way materials are stored, including segregation, labelling systems and controls of stocks of cultures. **Subelements** 3.1 Inventory 3.2 Information and Records 3.3 Transfer of Biological Agents and Toxins 3.4 Monitoring and Control	
	3	**PATHOGEN AND TOXIN INVENTORY AND INFORMATION**	
	3.1	**Inventory**	

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CWA 4.4.4.2	3.1.1	An accurate and up-to-date biological agents and toxins inventory is established and maintained.	The inventory process should be based on risk and include: a. identifying all biological agents and toxins held, including cultures, specimens and other sources (e.g. infected tissues/ samples or animals); b. restricting access to biological agents and toxins to authorized individuals with a demonstrable legitimate need; c. implementing effective physical security measures according to risk (e.g. locks, alarms, access controls); d. developing and maintaining a reliable sample identification system; e. segregating and storing biological agents and toxins according to risk; f. determining what materials should be controlled (e.g. seed stocks, working stocks, infected animals) and what level of information should be captured in the inventory for these materials.
	3.2	**Information and Records**	
CWA 4.4.4.2	3.2.1	Records related to the biological agents and toxins inventory are: 1. current; 2. complete; 3. stored securely with adequate backup provision.	Inventory information should include: a. the name(s) and contact information of the individuals(s) responsible for the poliovirus material, and the details of other personnel with access to the poliovirus materials or the immediate area based on the level of risk; b. restricted access to the detailed inventory records to those individuals whose work requires access to that information; c. legible and robust identification numbers and other relevant identifiers; d. records of quantities/volumes of biological agents and toxins at an appropriate level and based on risk (i.e. for certain biological agents, the details of the location and responsible individual may be adequate while for others more information may be necessary);

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			e. origin, including geographical source and date of collection; f. records of materials consumed, destroyed or removed from the facility.
	3.3	**Transfer of Biological Agents and Toxins**	
CWA 4.4.4.2	3.3.1	Transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of risk.	Controls should be put in place to ensure all the necessary checks and documented assurances are received to guarantee that requests for biological agents and toxins originate from legitimate facilities and individuals. Material may only be brought into the facility or sent elsewhere if authorized by those responsible for the facility. For materials deemed to be of high risk, more stringent controls, including shipment tracking and the verification of receipt, are necessary.
	3.4	**Monitoring and Control**	
CWA 4.5.3	3.4.1	The inventory is reviewed at predetermined intervals based on risk, and at a level and frequency whereby materials can be accounted for in an appropriate manner.	The nature of the inventory and associated controls should be based on the nature of the material held and on the risk of harm should it be misplaced or removed with the intention of misuse. The checks for many biological agents and toxins may be of a lower frequency and stringency than for others with greater potential for causing harm. Such measures may include the numbered sequences of tubes, periodic inspections and cross-checks with records of materials held.
CWA 4.5.3	3.4.2	Measures are put in place to minimize the quantities of biological agents and toxins in the inventory.	The organization should demonstrate proactive measures to reduce risk through the elimination, substitution or minimization of volumes/quantities of biological agents and toxins used, and the number of manipulations conducted. Procedures should be in place to investigate potentially missing biological agents.
		Element 4 – General Safety The General Safety element examines the processes in place to make sure	

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		hazards associated with the personnel's work in the facility are identified and managed while addressing their implications for biorisk. Both a preventive and proactive approach should be taken to establish measures to identify, detect, mitigate and respond to emergencies related to general safety, such as fire, electricals, radiation, chemicals, animal care and pressurized equipment. **Subelement** 4.1 General Safety	
	4	**GENERAL SAFETY**	
	4.1	**General Safety**	
CWA 4.4.4.1	4.1.1	A formal process is in place to identify and manage risk associated with general safety.	The organization should adopt a preventive and a proactive approach to managing such sources of risk, both to protect workers from the direct hazards associated with their work and to address the implications for biorisk in the event of an accident/ incident resulting from such sources. Measures should be identified and implemented to detect, mitigate and respond to emergencies, taking into consideration the potential implications for biological agent and toxin control in such measures. Issues addressed should include but are not limited to: a. general laboratory safety; b. fire safety; c. electrical safety; d. radiation safety; e. chemical safety; f. the use of gasses (including risk of asphyxiation); g. hot work and cold work; h. equipment under pressure; i. laboratory animal care and use; j. general housekeeping, including storage requirements and tidiness.

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		Element 5 – Personnel and Competency The Personnel and Competency element covers the processes in place to ensure that people with appropriate qualifications and backgrounds are recruited, that they are subsequently trained in all aspects of the work programme, and that their competency is assessed and monitored in a structured way. Other issues dealt with include how capacity issues are addressed and staff turnover is managed to ensure the organization is not left vulnerable when critical roles are vacated. **Subelements** 5.1 Recruitment 5.2 Training 5.3 Competence 5.4 Continuity and Succession Planning 5.5 Exclusion	
	5	**PERSONNEL AND COMPETENCY**	
	5.1	**Recruitment**	
CWA 4.4.2.1	5.1.1	Qualifications, experience and aptitudes related to biorisk are considered as part of the recruitment process.	Prior to employing a candidate, the organization should ensure that: a. all personnel in the poliovirus facility should be subject to a formal selection process, including relevant background checks based on risk (e.g. employment references, security checks); b. appropriate controls are implemented should existing employees be transferred to areas where there may be an increased risk profile; c. an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students), and measures are implemented to ensure they are applied where necessary.

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	5.2	**Training**	
CWA 4.4.2.4	5.2.1	Requirements and procedures for biorisk-related training of personnel are identified, established and maintained.	Procedures should: a. define biorisk training needs, b. provide the required biorisk training; c. determine the effectiveness of the biorisk training; d. provide refresher biorisk training; e. restrict personnel from performing tasks for which they are not trained; f. maintain adequate records. Training should include raising awareness of biorisk issues among the personnel, including the relevance of human factors in biorisk management.
	5.3	**Competence**	
CWA 4.4.2	5.3.1	Personnel who have responsibilities and/or perform tasks within the poliovirus facility that may impact biorisk management in the workplace are competent to do so.	Competence is defined in relation to appropriate education, training and/or experience, together with a demonstrable ability to perform the task in a safe/secure manner. Procedures should: a. define competency needs; b. lead to the successful completion of the required training; c. lead to the ability to perform tasks under supervision and unsupervised; d. restrict personnel who have not demonstrated competence from performing tasks for which they are not eligible; e. maintain adequate records. No worker should be exempt from demonstrating competence, irrespective of rank, experience or background.
CWA 4.4.2	5.3.2	Competence levels are judged on appropriate: 1. education; 2. training;	

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		3. experience.	
CWA 4.4.2	5.3.3	The organization has defined required levels of competency.	
CWA 4.4.2	5.3.4	Records are maintained that show staff members have attained and demonstrated those levels of competency.	
CWA 4.4.2	5.3.5	Personnel who conduct activities within the facility are under close supervision until they have demonstrated competency.	
	5.4	**Continuity and Succession Planning**	
CWA 4.4.2.3	5.4.1	Adequate backup and contingency measures are in place to address the need for continuity and succession planning.	The organization should identify roles and individuals that require a substitute, ensuring the integrity of the facility is not compromised through short- or long-term absence. Such measures should include succession planning for personnel (technical, management and scientific, including contractors) to guarantee that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of that individual's departure or unavailability.
	5.5	**Exclusion**	
CWA 4.4.4.7.3	5.5.1	Measures are put in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility, where deemed necessary through risk assessment.	The measures should: a. remove access to the facility (e.g. taking away passes, changing locks and keys and access codes, and other security devices); b. withdraw access to information related to the facility, including documentation, computerized records and data; c. allow the immediate physical removal of personnel if deemed necessary.
		Element 6 – Good Microbiological Technique The Good Microbiological Technique element examines how an organization identifies appropriate microbiological techniques and controls, and how they are implemented and reviewed. A major part of this	

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		element is the development of a biosafety or operations manual, which identifies hazards that may be encountered and specifies practices and procedures designed to minimize or eliminate risks. **Subelement** 6.1 Good Microbiological Technique	
	6	**GOOD MICROBIOLOGICAL TECHNIQUE**	
	6.1	**Good Microbiological Technique**	
CWA 4.4.4.5.1	6.1.1	All personnel handling biological agents and toxins are competent in good microbiological techniques.	
CWA 4.4.4.5.1	6.1.2	Appropriate resources (including time and equipment) are available to ensure good microbiological techniques are adhered to effectively.	As appropriate, procedures should address risks associated with but not limited to the following: a. animal handling; b. centrifugation; c. the control of needles and sharps; d. the correct use of vacuum pumps; e. culture, purification and storage techniques; f. the minimization/containment of aerosols; g. pipetting; h. sonication and other mechanical forms of cell/tissue disruption; i. the use of biological safety cabinets (BSCs); j. the use of disinfectants, including spill control, routine decontamination, hand washing and showering. This list is not exhaustive and identifies only some activities that may be employed during typical laboratory work. These activities should be undertaken in association with appropriate procedures and working practices to ensure the control measures are effective under all foreseeable and credible operating scenarios.

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			Appropriate control measures should be identified during risk assessments; these will vary depending on the biological agents and toxins being used and the activities to be undertaken.
		Element 7 – Clothing and Personal Protective Equipment (PPE) The Clothing and PPE element examines how an organization ensures that staff is provided with the right tools to minimize potential exposures, and that they know how and when to use them. This element specifically addresses the characteristics of some key items, for example the use of respirators and positive pressure suits, but also considers other commonly used items, including gloves, laboratory coats and footwear. **Subelement** 7.1 Clothing and Personal Protective Equipment (PPE)	
	7	**CLOTHING AND PERSONAL PROTECTIVE EQUIPMENT (PPE)**	
	7.1	**Clothing and Personal Protective Equipment (PPE)**	
CWA 4.4.4.5.4	7.1.1	PPE needs are identified.	Measures in place should include: a. ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback); b. ensuring all personnel who must use PPE, including scientific staff, visitors and contractors, are identified and supplied with correctly fitting equipment and clothing; c. explicitly addressing the selection and use of PPE in SOPs, training and competency assessments; d. defining and conducting an appropriate programme to ensure routine checks and the maintenance of PPE are defined and carried out; e. defining and addressing the need for and provision of replacement and spare PPE;

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			f. identifying and controlling the hazards associated with PPE itself (e.g. impaired dexterity or visibility); g. providing adequate PPE for use during both normal and emergency working conditions; h. ensuring procedures are in place for the cleaning and, if appropriate, the validated decontamination of used PPE, including safe storage prior to decontamination. PPE should be used in conjunction with, but never as a substitute for, reasonable and appropriate administrative and engineering controls. PPE should be used in accordance with established standards and manufacturer specifications. Employers should make PPE available to employees at no cost.
CWA 4.4.4.5.4	7.1.2	Suitable equipment is specified, made available, used and maintained appropriately within the facility.	
		Element 8 – Human Factors The Human Factors element is critical in any biorisk management programme, addressing issues as diverse as raising awareness of biorisk issues to initiating change management, and measuring and improving an organization's biorisk culture. Creating an environment where people are confident in reporting what has gone wrong and eliminating a "blame culture" are also addressed. **Subelement** 8.1 Human Factors	
	8	**HUMAN FACTORS**	
	8.1	**Human Factors**	
CWA 4.4.4.7	8.1.1	The organization has established and maintains a programme to address risk associated with human behaviour, including the management of how workers interact with the facility and its equipment.	The organization should ensure that factors associated with behaviours, and the need for individual support and communication, are managed responsibly, both to protect

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			workers from direct hazards and to ensure they can function optimally within the facility. Many laboratory incidents are caused by inappropriate behaviour or human frailties, and a preventive and proactive approach to managing risk associated with the individual should be pursued, including the specific inclusion of such issues in risk assessments. The use of competent experts in assessing this area should be considered. Measures should be put in place to address: a. human reliability and behavioural safety, including adherence to procedures; b. communication, consultation and feedback; c. conflict management and resolution; d. empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified; e. the avoidance of a "blame culture", including willingness to report accidents, incidents or unsafe conditions/behaviours, and protection of workers who do so; f. ergonomics, including equipment and work practice design to take account of individual needs; g. respect for individual privacy and dignity
		Element 9 – Health Care The Health Care element evaluates the systems in place to protect workers from injuries and illnesses resulting from exposures to biological agents or their products, and how they are supported in the event of an accident. Subject areas covered include exposure control, health care and monitoring, immunization and the availability of competent first aid and external assistance. **Subelements**	

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		9.1 Worker Health Programme 9.2 Vaccination of Personnel 9.3 Medical Emergencies	
	9	**HEALTH CARE**	
	9.1	**Worker Health Programme**	
CWA 4.4.4.6	9.1.1	The organization ensures that the risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively, including through preventive and protective measures.	The programme should address the needs of all individuals associated with the facility, including providing assurance that contractors and visitors receive the required level of protection in line with the activities they perform, as well as safeguarding workers' families.
CWA 4.4.4.6	9.1.2	The requirements of the health surveillance programme are determined by a defined health hazard identification and risk assessment process that involves all relevant personnel.	The programme may consult relevant personnel, including: a. the biorisk management adviser; b. the occupational health professional; c. facility personnel and employee representatives; d. external experts, including emergency responders; e. biorisk management committee members; f. veterinary and animal-care facility staff; g. human resource representatives; h. the communicable disease specialist; i. scientific management. Personnel considered to have significant risk of exposure should be identified and their health-care needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation/testing in the event of exposure. The individual's health and immune status should be considered, and periodic checks appropriate to work conditions should be established.

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			Although the primary focus of the assessment is exposure to the biological agents and toxins being handled, other conditions that could impact personnel associated with the facility should also be addressed. These may include medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility/dexterity), the ability to safely use appropriate PPE, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status). Information covered by the worker health programme should be treated confidentially. All individuals should have access to health-care consultation with either a corporate or institutional occupational health facility or an independent health-care provider, and be informed of the nature of any treatments/ vaccinations they may receive and their inherent risks and benefits.
	9.2	**Vaccination of Personnel**	
CWA 4.4.4.6.1	9.2.1	Based on risk, the need for vaccination has been determined and covers groups identified as being potentially exposed to biological agents and toxins.	Measures should be implemented when needed to identify non-responders to vaccination (depending on the vaccine's response rate) and a policy should be in place to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas with risk of exposure. Areas requiring vaccinations to enter should be posted. Visitors, contractors and other non-core personnel should provide evidence of vaccination or of established immunity in accordance with the above requirement. Based on risk, reasonable measures should be taken to ensure that the vaccinations have been given and current certificates are valid. This may include examining original certificates and cross-checking with medical practices

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			responsible for administering the vaccine. The organization should ensure the required or recommended vaccines are made available to concerned personnel. Vaccination should be seen as a risk-mitigation strategy, and its use should in no way infer that other controls, such as the use of good microbiological techniques or PPE, can be relaxed.
CWA 4.4.4.6.1	9.2.2	A vaccination policy has been defined and implemented.	
CWA 4.4.4.6.1	9.2.3	Access to laboratories or work is controlled for individuals until they comply with the vaccination policy.	
	9.3	**Medical Emergencies**	
CWA 4.4.5.2	9.3.1	A system is established to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers.	Procedures should ensure that adequate emergency planning is provided to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, to members of the broader community and to environmental conditions that may have been affected by the incident. It should include identifying emergency scenarios (e.g. involving an infected worker/family member) and necessary support measures (e.g. liaison with emergency services/local authorities), and providing equipment and other resources required to manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained. Procedures should ensure that adequate first aid is available in relation to credible accident scenarios, as identified during risk assessments. The procedures should address the need for

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			adequately trained personnel and their availability, as well as equipment and other materials that may be required to provide treatment. Procedures should ensure additional competent medical support is identified and made available (e.g. hospitals, isolation units).
		Element 10 – Emergency Response and Contingency Planning The Emergency Response and Contingency Planning element examines the structures and mechanisms in place to cope with working outside normal operating conditions, and how to react proportionally to emergency situations. Issues addressed include physical requirements, capacity in terms of personnel and facilities and of protective and rescue systems, emergency communications, decision-making authorities and the development and testing of emergency scenarios and simulations. **Subelements** 10.1 Emergency Scenarios 10.2 Emergency Response and Planning 10.3 Emergency Plans 10.4 Emergency Exercises and Simulations 10.5 Contingency Plans	
	10	**EMERGENCY RESPONSE AND CONTINGENCY PLANNING**	
	10.1	**Emergency Scenarios**	
CWA 4.4.5.1	10.1.1	All credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.	To plan for emergencies, all credible emergency scenarios must be considered. It is unlikely that all potential scenarios will be credible, but all reasonable threats should be considered and recorded and, where appropriate, the rationale for dismissing any issue should be provided.

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			Scenarios considered should include: a. an infected/potentially infected worker or other contact (e.g. family member, emergency responder or community member); b. accident or illness to a worker within the containment area and need for evacuation; c. fire; d. flood; e. breach of security; f. explosion; g. the potential loss of biological agents or toxins through theft or any other reason; h. unexpected virulence (unknown biological agents or biological agents expected to be avirulent); i. physical facility and equipment failure, including a control system failure of the disinfection regime; j. utility failure including electricity, gas, steam and water supplies; k. a major spillage/aerosol release; l. environmental release; m. a natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics); n. an act of terrorism or deliberate vandalism; o. intense media attention.
	10.2	**Emergency Response and Planning**	
CWA 4.4.5	10.2.1	Plans and procedures are established and maintained to: 1. identify the potential for incidents and emergency situations involving biological agents, toxins and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them.	

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CWA 4.4.5	10.2.2	Emergency planning covers all aspects of biorisk and includes general safety, security and medical issues.	
	10.3	**Emergency Plans**	
CWA 4.4.5.2	10.3.1	Biorisks are taken into account when preparing and implementing emergency plans.	The organization should ensure that plans address the following needs at a minimum: a. identifying those responsible for devising, implementing and testing the control measures; b. responding during emergencies occurring outside working hours as well as those occurring during normal working hours; c. providing for periods of reduced staff availability (e.g. during weekends and holiday periods); d. ensuring emergency access/exit, including the ability to override access controls as appropriate; e. providing emergency exit routes that avoid evacuating people through containment areas; f. providing for the safe removal, transport, transfer, treatment and accommodation of contaminated persons and objects.
CWA 4.4.5.2	10.3.2	Control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency.	
CWA 4.4.5.2	10.3.3	Emergency plans are effectively communicated to all employees and relevant third parties, and tested with the goal of making everyone aware of their obligations.	In the event of an emergency situation, it may be necessary to involve parties external to the organization. Based on the credible scenarios identified, the organization should pinpoint such agencies to establish their role in responding to a given situation. The organization may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties on their role and any risk exposures they may face, and ensure their actions will not unnecessarily increase the risk associated with the emergency (e.g. uncontrolled use of water for fires). Contact

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			information should be documented and made available to personnel responsible for coordinating the emergency response activity. External agencies consulted may include: a. police and security services; b. fire services; c. ambulance and local hospitals/health-care providers; d. transport providers/couriers; e. local and national government officials; f. environmental authorities.
	10.4	**Emergency Exercises and Simulations**	
CWA 4.4.5.3	10.4.1	Structured and realistic emergency exercises and simulations, including security drills, are conducted at regular intervals based on risk, to test the plans, prepare personnel and learn from any good practices or deficiencies identified.	Exercises and simulations should be conducted to provide assurance that plans are effective and to learn from any lessons that arise. Exercises should be planned and every effort made to ensure they realistically represent the events simulated. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of an exercise should be documented and reviewed for lessons learnt, and feedback on performance should be provided to the appropriate personnel. Any resulting actions should be recorded and allocated to named individuals, and measures should be put in place to ensure they are closed out effectively.
	10.5	**Contingency Plans**	
CWA 4.4.5.4	10.5.1	In the event of an emergency, adequate contingency measures are in place to ensure the safety and security of continued operations.	Normal operating conditions may be disrupted in the event of an emergency or unforeseen event. This could range from

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			safely shutting down work during a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively, and contingency plans put in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems (e.g. power supplies), alternative means of decontaminating materials in the event of the failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shutdown of operations in extreme situations.
		Element 11 – Accident/Incident Investigation The Accident/Incident Investigation element addresses activities that define the facts and circumstances related to an event, determine the causes and develop remedial action to control biorisk and prevent recurrence. Often, chance is the only reason a property-damage accident or near-miss incident does not result in infection or personal harm. Likewise, chance alone often determines whether an accident's consequences are minor, serious or catastrophic. This element examines the organization's reporting and investigation system, whether the right people are involved and how corrective and preventive actions are implemented. **Subelement** 11.1 Accident/Incident Investigation	
	11	**ACCIDENT/INCIDENT INVESTIGATION**	
	11.1	Accident/Incident Investigation	
CWA 4.5.4.1	11.1.1	Documented procedures are established and maintained to define, record, analyse and learn from accidents and incidents involving biological agents and toxins.	Procedures should be put in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel. It may include events

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			of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed; it is essential that lessons be learnt and improvements made where possible. The accident/incident investigation process should include at a minimum: a. identifying those responsible for maintaining the accident/ incident reporting system; b. defining what constitutes an accident/incident and what triggers recording and reporting, with emphasis on events that may result in exposure to live poliovirus (e.g. sticks, spills, splashes, sprays, leaks, aerosol generating events); c. specifying required documentation to support the system; d. identifying the reports that will be generated, as well as their frequency and distribution; e. ensuring an analysis of trends; f. identifying root causes using individuals trained in investigation techniques; g. providing feedback at regular intervals and action-tracking mechanisms to ensure lessons learnt result in action to avoid repeating such events and/or to minimize their potential impact; h. identifying where security professionals may be required to coordinate with law enforcement.
		Element 12 – Facility Physical Requirements The Facility Physical Requirements element looks at how the organization addresses biorisk during periods when something new is introduced or the existing set-up is changed. Issues addressed include identifying the people who need to be involved and consulted, incorporating biorisk into planning, approaching commissioning in a structured way (including the role of suppliers), considering the physical characteristics of the materials used and carrying out any certification that may be needed.	

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		Subelements 12.1 Planning, Design and Verification 12.2 Commissioning and Decommissioning 12.3 Infrastructure and Operational Management	
	12	**FACILITY PHYSICAL REQUIREMENTS**	
	12.1	**Planning, Design and Verification**	
CWA 4.4.4.8.1	12.1.1	A formal planning, design and redesign process is adopted for the facility, based on an assessment of risk associated with the materials to be used and activities undertaken.	A formal design process means a structured and documented approach, whereby the facility's needs are determined through risk assessment. Engineering and operational solutions will be incorporated that are consistent with the risk posed by the properties of the materials to be stored and handled in the facility and the nature of the work to be carried out.
CWA 4.4.4.8.1	12.1.2	The design process identifies and incorporates all relevant legislative requirements, together with information from recognized standards, guidelines, industry good practices and facility-specific risk assessments.	The design process should include identifying and reviewing relevant legislation and codes of practice (including building codes as well as those related to laboratory biosafety/laboratory biosecurity) and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and standards of acceptance to ensure performance. The process should be documented and transparent to provide assurance that it has been comprehensive and thorough.
CWA 4.4.4.8.1	12.1.3	The design process identifies and facilitates consultation with all relevant parties associated with the facility and its operation.	The design process should include identifying and consulting with individuals involved in the planning, construction, operation and maintenance of the facility. The following roles/individuals should be considered in terms of information requirements and consultation: a. scientific personnel and other end users; b. the biorisk management adviser and biorisk management committee;

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			c. biosecurity and/or security personnel; d. designers (architects and engineers); e. constructors; f. maintenance engineers; g. material and equipment suppliers; h. commissioning agents; i. certifiers; j. regulators; k. first responders; l. other relevant parties identified in risk assessments. If justified, and based on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specifications: a. are in line with accepted good practice; b. incorporate features capable of providing assurance regarding the control of biological agents and toxins; c. integrate relevant legislative requirements, as well as standards and risk assessment findings, in the design.
CWA 4.4.4.8.1	12.1.4	All design features, construction techniques, materials and equipment selected are documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specifications.	
CWA 4.4.4.8.1	12.1.5	New construction and physical facility modifications are carried out according to an approved plan.	
	12.2	**Commissioning and Decommissioning**	
CWA 4.4.4.8.2	12.2.1	A formal process exists for: 1. the initial commissioning of new facilities; 2. the final decommissioning of existing facilities.	Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase during the first stage of science programme definition to ensure the expectations for the building are

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			achievable. The commissioning plan should be developed in detail in parallel with the physical concept to ensure the expectations for the building are measurable. The commissioning plan should clearly identify all the steps from beginning to end, providing examples and including the conditions of acceptance of each step as a prerequisite for proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after any temporary shutdown. The commissioning process should provide the benchmark for acceptable facility operation and the description of the programme to be put in place to maintain that level of performance. The decommissioning process should identify the decontamination procedures and security-related measures that must be in place for the facility's temporary or final shutdown. The decommissioning programme should describe not only the procedures, but also the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned facility can be re-entered.
	12.3	**Infrastructure and Operational Management**	
CWA 4.4.4.8	12.3.1	Facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management.	
		Element 13 – Equipment and Maintenance The Equipment and Maintenance element aims to ensure that biorisk is	

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		taken into consideration during the selection of all equipment that has implications for its control. Emphasis is placed on selection procedures, the maintenance of asset registers, control over where the equipment may be moved, and what it will be used for over its working life. Particular attention is also given to ensuring the equipment functions properly by following prescribed periodic and predictive maintenance, supported by adequate breakdown response. **Subelements** 13.1 Maintenance Management 13.2 Control of Equipment 13.3 Calibration 13.4 Certification 13.5 Validation	
	13	**EQUIPMENT AND MAINTENANCE**	
	13.1	**Maintenance Management**	
CWA 4.4.4.8.3	13.1.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are maintained in a manner consistent with the intent and requirements of the biorisk management programme.	The maintenance programme should apply to all aspects of the physical structure (including finishes and seals, where appropriate) and equipment therein. All materials used should be specified to ensure they can perform in line with predetermined criteria. An appropriate maintenance plan will be addressed as part of that specification process. In planning and conducting maintenance activities, the organization should consider: a. adequately maintaining the facility's physical integrity and its fixtures and fittings; b. ensuring competent individuals perform the maintenance activities, and the risks associated with the work have been subjected to a risk assessment;

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			c. ensuring adequate controls are in place to prevent workers from being exposed to poliovirus during their work; d. identifying and recording maintenance requirements during the construction of facilities or when equipment is purchased/ acquired; e. creating and maintaining a maintenance register for all applicable equipment; f. identifying and conducting planned maintenance activities at an appropriate frequency; g. ensuring unplanned (breakdown) maintenance is adequately provided for so the facility's integrity is maintained at all times; h. determining and monitoring predictive maintenance requirements and associated indicators and monitors; i. ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement; j. establishing a pest control programme.
	13.2	**Control of Equipment**	
CWA 4.4.4.8.3	13.2.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are controlled in a manner consistent with the intent and requirements of the biorisk management programme.	In planning and conducting equipment controls, the organization should consider: a. identifying equipment in line with work needs, which can be demonstrated as fit for purpose; b. controlling the purchase/acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel; c. controlling the entry and exit of equipment to and from the poliovirus facility, including decontamination requirements (e.g. air locks and decontamination).
	13.3	**Calibration**	

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CWA 4.4.4.8.3	13.3.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are calibrated in a manner consistent with the intent and requirements of the biorisk management programme.	In planning and conducting calibration activities, the organization should consider: a. identifying and recording calibration requirements at the time of purchase/acquisition; b. identifying the standards/tests to use to ensure the equipment is correctly calibrated; c. establishing procedures to conduct calibrations on equipment used in live virus areas; d. creating a documented and up-to-date calibration register for all applicable equipment; e. ensuring calibration is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.4	**Certification**	
CWA 4.4.4.8.3	13.4.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are certified in a manner consistent with the intent and requirements of the biorisk management programme.	In planning and conducting certification activities, the organization should consider: a. identifying and recording certification requirements at the time of purchase/acquisition of equipment, including relevant and current standards against which to certify; b. ensuring competent and independent certifiers are used for the certification process; c. ensuring certification is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments.
	13.5	**Validation**	
CWA 4.4.4.8.3	13.5.1	Documented procedures are established and maintained to ensure equipment and elements of the physical plant that may have an impact on biorisk are validated in a manner consistent with the intent and requirements of the biorisk management programme.	In planning and conducting validation activities, the organization should consider: a. identifying and recording validation requirements at the time of purchase/acquisition;

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			b. identifying the standards/tests to use to ensure the equipment is correctly validated; c. creating a documented and up-to-date validation register for all applicable equipment; d. ensuring validation is scheduled and conducted in line with manufacturer requirements and/or at other specified intervals as identified by risk assessments; e. ensuring competent and independent validation mechanisms are used for the validation process. For physical security systems, the analogous concept is performance testing and evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed.
		Element 14 – Decontamination, Disinfection and Sterilization The Decontamination, Disinfection and Sterilization element examines the controls in place to ensure that appropriate disinfection, decontamination and sterilization routines manage the risk presented by the organisms and work activities undertaken. The element addresses general requirements for procedures, training and waste disposal as well as more specific issues, including the potential need for specialist laundering and issues specific to animal facilities. **Subelements** 14.1 Management of Biological Waste 14.2 Inactivation of Biological Agents and Toxins	
	14	**DECONTAMINATION, DISINFECTION AND STERILIZATION**	
	14.1	**Management of Biological Waste**	
CWA 4.4.4.5.3	14.1.1	The organization has established and maintains an appropriate waste management policy for biological agents and toxins.	The organization should have a validated procedure for the inactivation of biological agents and toxins and their waste

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		No viable poliovirus will be released from the facility unless approved by the competent authority for transfer to another approved facility under controlled conditions. Potential routes whereby viable poliovirus could unintentionally exit the facility will be identified and adequate prevention measures put in place.	products. The following elements should be considered for a waste management policy: a. ensure a programme is in place to minimize waste production; b. ensure effective waste audit trails are in place and documented; c. provide adequate facilities and procedures for the storage of waste (including short-term storage); d. ensure methods are available to effectively segregate and decontaminate mixed waste (e.g. infected animals that have received radioactive materials); e. ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transport.
CWA 4.4.4.5.2	14.1.2	All contaminated or potentially contaminated waste items (including those that may result from an emergency) have been: 1. identified; 2. documented.	Sources of contamination that should be considered include: a. personnel; b. clothing and PPE; c. glassware; d. equipment; e. cultures and associated materials; f. spill clean-up materials and equipment; g. possibly infectious microorganisms, toxins and contaminated materials; h. paper and plastic waste; i. needles, syringes and sharps; j. waste water, including that from sinks and showers; k. air; l. filters and air handling systems; m. discarded equipment used in the facility; n. animals exposed to laboratory biological agents and toxins; o. animal carcasses and bedding; p. facilities. All potential waste streams and other sources of contamination should be identified and documented.

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CWA 4.4.4.5.2	14.1.3	Efficient procedures are in place to devise effective decontamination and other appropriate treatments.	Contaminated personnel may include core personnel working within the facility, contractors and emergency response personnel. Cultures and associated materials may be a source of contaminated supernatants, aspirates and culture media. Infected biological materials may also include infectious human, animal or plant specimens. In some instances, contaminated dedicated equipment, such as fire-fighter apparel or ambulance tools, may need to be held on-site if they cannot be effectively decontaminated. Risk assessment should be an integral part of the process to identify and develop effective decontamination regimes.
	14.2	**Inactivation of Biological Agents and Toxins**	
CWA 4.4.4.5.2	14.2.1	Procedures are established and maintained to ensure appropriate disinfection and decontamination methods are chosen and implemented effectively.	Whatever biological agents and toxins are handled, a number of effective inactivation methods are likely to be available. The organization should ensure data are available to demonstrate that the methodology selected is capable of inactivating the biological agents and toxins under the specific conditions encountered in the facility. Validation measures should consider such issues as: a. the nature of the material being treated (e.g. volume, presence of protein/other potentially inhibitory substances); b. contact times, material compatibility issues (e.g. interaction with stainless steel or rubber seals); c. potential health hazards associated with the disinfectant; d. the need to maintain the required level of active compound, including deterioration over time. In planning and conducting decontamination activities, the

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			organization should consider: a. ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and such concentrations are maintained throughout the process, including conducting specific validation activities where necessary; b. providing adequate facilities and procedures for the storage of waste (including short-term storage); c. ensuring methods are available to effectively decontaminate mixed waste (e.g. infected animals that have received radioactive materials); d. ensuring methods are available, where appropriate, to decontaminate sensitive equipment not suitable for autoclaving (e.g. computers); e. implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and the use of indicators in autoclaves); f. decontaminating protective clothing by appropriate means prior to leaving the facility; g. ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during the handling and transport of materials inside and outside the facility; h. implementing programmes to ensure the amount of contaminated waste is minimized.
		Element 15 – Transport Procedures The Transport Procedures element explores how an organization deals with issues associated with the internal and external transport of biological materials, and looks at the necessary roles and responsibilities, materials and equipment, as well as the need to work with specialist couriers and shipping agents.	

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		Subelement 15.1 Transport Procedures	
	15	**TRANSPORT PROCEDURES**	
	15.1	**Transport Procedures**	
CWA 4.4.4.9	15.1.1	Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.	In planning and conducting transport activities, the organization should consider: a. ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines; b. ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transport process; c. selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely; d. determining whether a request for biological agents and toxins, or material that may contain viable biological agents and toxins, is being made by an approved facility for a legitimate reason, and equivalent controls are applied to the importation of material to the facility; e. identifying the need for formal documented transfer forms signed by the responsible management representative authorizing the movement of the materials; f. using document controls that allow the traceability of material movements; g. identifying and implementing adequate and proportionate emergency response and contingency plans associated with the transport, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off.

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		Element 16 – Security The Security element examines how an organization manages security with regard to biorisk. The element looks not only at some of the more obvious issues, such as access control, but also at the need for information security and support from external agencies. **Subelements** 16.1 Physical Security 16.2 Information Security 16.3 Personnel Control 16.4 Personal Security 16.5 Contractors, Visitors and Suppliers	
	16	**SECURITY**	
	16.1	**Physical Security**	
CWA 4.4.4.8.4	16.1.1	Controls are implemented and maintained for the physical security of cultures, specimens, samples and potentially contaminated materials or waste, determined as part of the risk assessment process.	Measures should be put in place to minimize the potential for release or removal of biological agents from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms. In planning and conducting security risk assessments, the organization should consider: a. the theft or diversion of biological agents and toxins or related equipment, documents or data; b. sabotage, including vandalism and tampering; c. break-in and intrusion; d. labour issues and disputes; e. weather-related emergencies (e.g. earthquake, tsunami, flood, tornado, hurricane);

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			f. workplace violence; g. the failure of utilities; h. picketing, occupation and barricade; i. the screening and isolation of suspect packages; j. acts of terrorism; k. civil unrest or war. Care should be taken to coordinate biosecurity and biosafety measures to manage and minimize conflicting priorities. Security breaches should be reported, recorded and investigated as accidents and incidents.
	16.2	**Information Security**	
CWA 4.4.4.8.5	16.2.1	A policy and procedure are in place to identify sensitive information.	The information generated by a laboratory can be as valuable and/or dangerous as the biological agents and toxins stored at the facility. Adequate measures to prevent the unauthorized release of such information are critical. Procedures addressing information security should consider: a. the secure storage of all sensitive written records and data, including electronic records and electronic signatures; b. computer security, including robust Internet firewalls and encryption protocols; c. strict policies regarding PCs, laptop computers, storage media and cameras, among others, entering or leaving the facility; d. the thorough destruction of paper files to be discarded, and complete erasure of unwanted electronic files.
CWA 4.4.4.8.5	16.2.2	A review and approval process is used to control access to sensitive information.	

CWA15793 Clause No.[23]	Biorisk Management Element No.	Safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential laboratories	Guidance
	16.3	**Personnel Control**	
CWA 4.4.4.7.1	16.3.1	A personnel reliability policy is defined and implemented.	The nature and extent of the measures required for the personnel reliability assessment should be determined as part of the risk assessment process. In some instances, few checks may be required other than collecting employment references, whereas, in others, more in-depth screening may be deemed necessary.
CWA 4.4.4.7.1	16.3.2	The organization ensures that individuals' access to facilities or work is controlled, according to the policy.	Where lawful and appropriate as determined by risk assessments, screening may include such checks as identity and immigration status, membership in organizations hostile to biological research, criminal records and financial probity.
	16.4	**Personal Security**	
CWA 4.4.4.10	16.4.1	A policy is in place to provide personal security support services to staff members, including, where appropriate, personal security awareness training.	Personal security is concerned with staff security during off-duty hours while away from the facility. During these times, staff members are vulnerable because of their function or position.
	16.5	**Contractors, Visitors and Suppliers**	
CWA 4.4.4.7.2	16.5.1	The organization ensures that suppliers, contractors, visitors and subcontractors adhere to the established management systems' requirements and do not compromise the facility's biorisk management.