# working draft
# GAPIII

## WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of routine OPV use

After type-specific eradication and containment of wild poliovirus and cessation of routine oral polio vaccination, minimizing the risk of poliovirus reintroduction is critical. In order 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.

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## Acknowledgements

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# Introduction

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

The *Polio Eradication & Endgame Strategic Plan* (the Endgame Strategy) *2013-2018* (World Health Organization, 2013), set the goal of a polio-free world by 2018. Achieving this goal requires: i) completion of eradication to eliminate risk of wild poliovirus (WPV) transmission; ii) cessation of the routine use of oral polio vaccines (OPV) to eliminate the risks of vaccine-associated paralytic poliomyelitis (VAPP), chronic vaccine-derived poliovirus infections of immunodeficient persons (iVDPV), and outbreaks of circulating vaccine-derived polioviruses (cVDPV), (Aylward RB et al., 2006); 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 toward cessation of routine 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 routine 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 a combination of 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 routine OPV use, bOPV will be the vaccine of choice for response to any WPV type 1 (WPV1) and WPV type 3 (WPV3) outbreaks, while monovalent OPV2 (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 VDPV outbreak.

Global consensus to stop bOPV will require international assurance that 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 that the risk from facility-associated reintroduction of wild or OPV/Sabin polioviruses can be minimized.

This 3rd 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 3rd edition posted on the GPEI web site and the 2nd edition of the *WHO global action plan for laboratory containment of wild polioviruses* (World Health Organization, 2004). The 3rd edition:

- Describes timelines and requirements to be

  - completed in preparation for *poliovirus type 2 containment*,
  - implemented throughout the *poliovirus type 2 containment period*, and
  - 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 routine OPV use after type-specific WPV eradication (World Health Organization, 2005);

- 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 (Fine PEM and Ritchie S, 2006), and management strategies (Annexes 2 and 3); and

- 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 the number of facilities handling and storing polioviruses to a minimum serving essential 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. The 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 oversight of work with poliovirus. 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 which can be demonstrably proven to be more attenuated, less pathogenic, and safer, a review of applicable controls relating to the use and handling of these organisms will be considered on a case by case basis using available evidence.

## 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 reestablishing poliovirus transmission. When routine use of OPV stops, many countries will continue high population coverage with IPV, other countries will have sub-optimal 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 (Fine PEM and Ritchie S, 2006).

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 essential international functions, including IPV and Sabin-IPV production, storage of OPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, together with crucial research.

Each of these essential poliovirus facilities should manage biorisk appropriately to minimize the risk of virus reintroduction into the community, with effective national and international certification programmes. The risk from a poliovirus reintroduction can be minimized by location of essential facilities in areas with good personal, domestic, and environmental hygiene standards, with high levels of population immunity, effective AFP and environmental surveillance, supplemented by efficient public health and response capacity. Consequences can be further minimized by working only with Sabin/OPV or alternative, more attenuated strains (REF?), which have lower basic reproduction rates ($R_0$) than WPV (Fine PEM and Ritchie S, 2006). Minimizing the number of 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 destruction of poliovirus materials in all but certified essential facilities[1] and *biorisk management* of such facilities by strict adherence to required safeguards.

### *Risk Elimination*

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

1. infectious and potentially infectious WPV materials and
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 which in the past worked with polioviruses (World Health Organization, 2005) and in non-polio facilities retaining valuable clinical materials potentially infected with polioviruses or OPV/Sabin materials.

Successful global elimination of risk requires each country to effectively prohibit retention and subsequent acquisition of poliovirus materials in all non-essential facilities following global recommendations (World Health Organization, 2013).

### *Biorisk Management*

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

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

National and international certification will provide assurance that the required safeguards are met.

*Primary safeguards* of containment reduce the likelihood for accidental or deliberate poliovirus release from an essential facility and are specified in the *Biorisk management standard for essential poliovirus facilities holding WPV materials* (Annex 2) and *Biorisk Management standard for essential poliovirus facilities holding only OPV/Sabin poliovirus materials* (Annex 3). Key elements include

[1] Laboratories or polio vaccine production facilities

- Facility management, which practices 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,

- Immunization (IPV) of facility personnel, which can reduce the risk of infection in the facility and intra- or extra-household transmission, should infection occur (Dowdle WR et al., 2006),

- Reduction in the use of WPV and substitution with Sabin strains or further attenuated strains where possible (Dowdle WR et al., 2006) (Tebbens RJD et al., 2004),

- 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 from an essential containment facility into the community and consist of a national routine childhood polio immunization policy and achieving high national population coverage consistent with WHO policy (e.g. the Endgame Plan) and eventual post-eradication strategies (World Health Organization, 2006).

*Tertiary safeguards* of facility location minimize the consequences of release of highly transmissible WPV by placement of essential facilities in areas with demonstrated low poliovirus reproductive rates ($R_0$), i.e. in areas with closed sewage systems with a minimum of secondary treatment of effluents.

Primary, secondary, and tertiary safeguards are required for essential facilities handling and storing WPV materials after WPV eradication (Table 1).

Primary and secondary safeguards are required for essential facilities handling and storing WPV or OPV/Sabin materials throughout the *Poliovirus type 2 containment period* and after cessation of routine OPV use (Table 1). The potential for spread ($R_0$) is 2-10 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 (Tebbens RJD et al., 2004).

*Annual national and triennial international certifications are required for all essential poliovirus facilities.*

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 |

[2] Since the operator is considered to be one of the sources of release of poliovirus from the facility, specific measures of protection are required, including e.g. the use of PPE, the use of primary containment devices, and vaccination

[3] Untreated release into closed sewage system with secondary effluent treatment in facility location (Note: all waste from facilities, potentially containing live poliovirus, should be inactivated prior to release through adequate and validated inactivation procedures. For facilities without a dedicated effluent treatment plant, this would normally be done through the application of 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 closed sewage system with secondary or greater effluent treatment in facility location

[5] HEPA (high efficiency particulate arresting) filtration on exhaust air

[6] Diphtheria-tetanus-pertussis (DTP3) immunization coverage (World Health Organization)

[7] (World Health Organization, 2013)

# 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 ongoing until the conditions for global readiness for OPV2 withdrawal have been met.

Key activities

- National laboratory survey and poliovirus type 2 inventory;
- Destruction of unneeded poliovirus type 2 materials;
- Transfer of needed poliovirus type 2 materials to essential facilities;
- Governments, institutions, and polio facilities informed about the upcoming need for poliovirus containment
- Designated essential facilities obtain certification for containment.

***Phase II: Poliovirus type 2 containment period***

Phase II commences as soon as readiness for OPV2 withdrawal is declared, and continues until certification of global eradication. Readiness criteria (WHA 67/38, 2014) for OPV2 withdrawal include:

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

The trigger for setting a definite date for the 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 wild poliovirus type 2 (WPV2)

- All WPV2 are contained as per Table 1 in essential facilities that have been certified in Phase I.

Phase IIb: Containment of OPV/Sabin type 2 (OPV2/Sabin2) polioviruses

- All OPV2/Sabin2 are contained as per Table 1 in essential facilities that have been certified in Phase I.

During Phase II action on OPV2/Sabin2 containment may be temporarily suspended in areas where a decision by WHO has been made to use mOPV2 (or tOPV) to respond to emerging or re-emerging 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 global certification.

Phase IIIa: Containment of all wild poliovirus

- All WPV are contained long term as per Table 1 in essential facilities that have been certified, with enhanced safeguards

Phase IIIb: Containment of all OPV/Sabin (OPV/Sabin) polioviruses

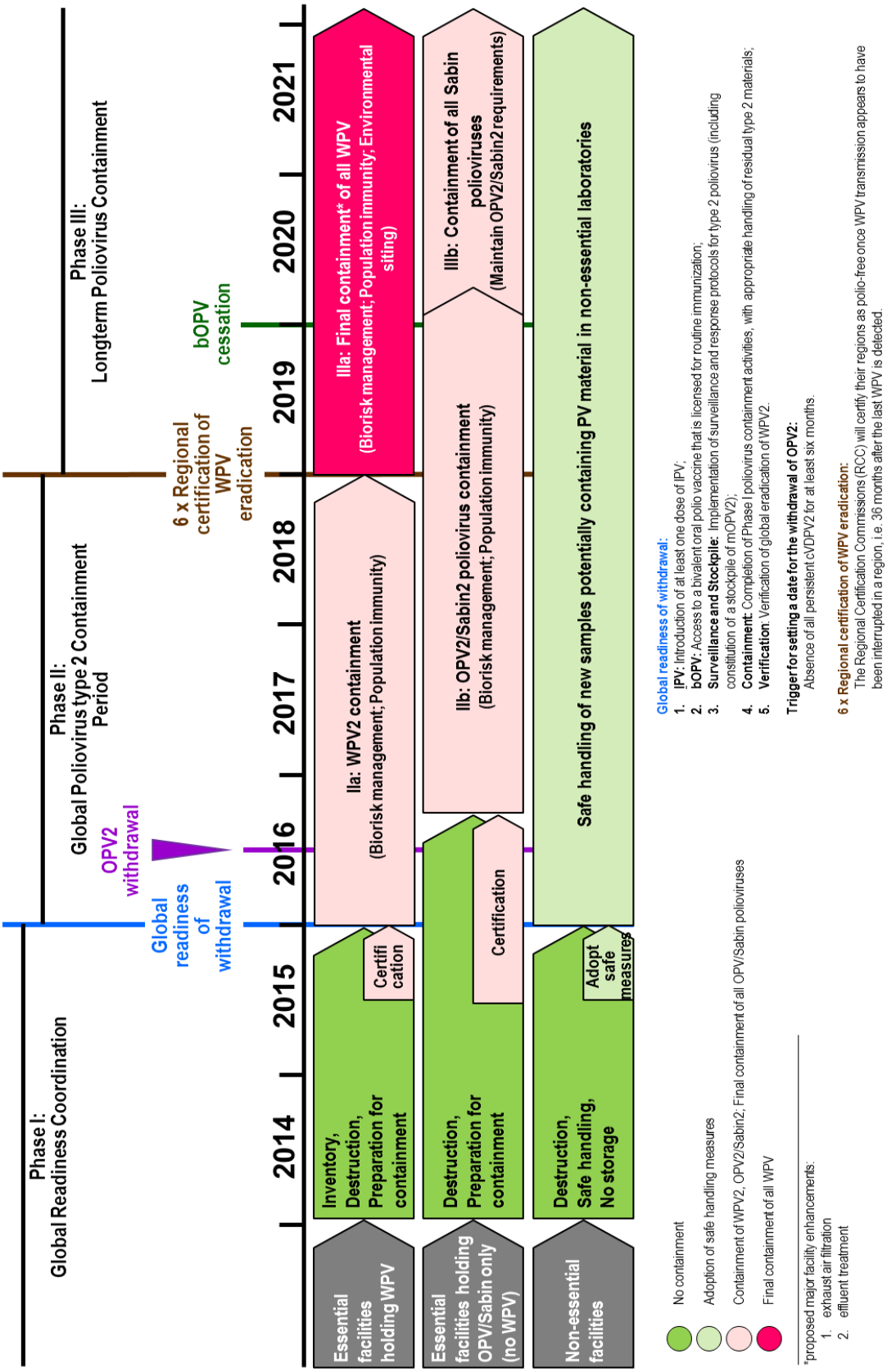
- All OPV/Sabin are contained long term as per Table 1 in essential facilities that have been certified

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

During phase III action on OPV/Sabin containment may be temporarily suspended in areas where an international decision has been made to use mOPV to respond to cVDPV transmission.

Implementation requirements for the different phases are described below.

Figure 1: Containment requirements



# Phase Implementation

### *Phase I: Preparation for containment of poliovirus type 2*

Phase I (*National survey; wild and OPV/Sabin poliovirus inventory; destruction of unneeded poliovirus type 2 materials; transfer of needed poliovirus type 2 materials to essential facilities, 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 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 on the database are surveyed in order to confirm whether wild poliovirus infectious or potential infectious materials are being stored.

- *Develop a national inventory of facilities that handle and store WPV materials, and report to the WHO Regional Commission for the Certification of Poliomyelitis Eradication , RCC).* 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 Regional Certification Commission on the current status of the National Inventory of facilities with poliovirus materials.*

- *Complete national surveys and inventories, and submit documentation to the Regional Certification Commission that Phase I survey and inventory requirements have been met.* The Ministry of Health (MoH) submits the complete report of Phase I survey and inventory activities, and supporting documents to the National Certification Committee for review and endorsement before submission to the Regional Certification Commission (*Guidelines for documenting the quality of Phase I wild poliovirus laboratory containment activities: laboratory survey, national inventory* (US Department of Health and Human Services HHS, 2003)).

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

- *Adopt international goals* (World Health Organization, 2013) *for timely destruction or containment of WPV2 materials and of OPV2/Sabin2 materials*, and decide to either
    - Prohibit retention of all specified poliovirus materials by any facility after achievement of specific milestones, or

- Prohibit retention of all GAPIII-specified poliovirus materials except in designated certified essential poliovirus facilities.

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

- *Alert biomedical facilities to national policies/international agreements (REF WHA resolution 2015) pertaining to retention of WPV materials or OPV/Sabin materials to permit 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* (Dowdle WR et al., 2006). 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 essential poliovirus research and reference facilities for handling and storage arrangements.

- *Request facilities on the national inventory to submit plans for compliance with poliovirus retention policies and/or regulations (REF WHA resolution 2015), including status of materials and action timelines.*

- *Request non-essential facilities that do not intend to retain infectious or potential infectious WPV materials* (World Health Organization, 2004) to
  - Destroy unneeded poliovirus material (WPV infectious and potential infectious materials, and any OPV/Sabin materials) or
  - Transfer all needed poliovirus material to essential poliovirus facilities.

- *Request non-essential laboratory facilities that are likely to handle, as of Phase II, new WPV2, aVDPV2, cVDPV2 or cVDPV2 isolates, or new faecal or respiratory samples originating from recent OPV-using countries, to adopt and implement*
  - *Safe and secure working practices* based on risk assessment and implementation of appropriate biorisk management systems (CEN, 2011), and
  - *A non-retention policy for WPV2 materials* as of the beginning of Phase IIa and of OPV2/Sabin2 materials as of the beginning of Phase IIb of the *Poliovirus type 2 containment period*.

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

- *Notify the general biomedical laboratory community that according to the globally endorsed Endgame Strategy* (World Health Organization, 2013) *retention of WPV2 materials will no longer be permitted in Phase IIa and retention of OPV2/Sabin2 materials will no longer be permitted in Phase IIb except in designated certified essential facilities.* Facilities are fully responsible for compliance with national policies and/or regulations, including destruction of WPV infectious and potentially infectious materials and any OPV/Sabin materials or the transfer of such materials to a designated essential facility. Facilities on the national database of biomedical laboratories with a history of performing activities placing them at risk of having potentially infectious WPV materials or contaminated stocks must respond to the MoH or other designated national authority documenting the absence of such materials.

Countries *with* plans to designate essential poliovirus facilities shall in addition

- *Request candidate facilities to assess and submit documentation demonstrating compliance with secondary and tertiary safeguards, as applicable to the type of material being held (WPV or OPV/Sabin poliovirus).*

- *Implement national certification procedures to assess compliance with 'Containment of poliovirus type 2' provisions, including primary and secondary safeguards.* All nationally certified essential facilities must then be certified internationally through WHO (Annex 4). Designated essential WPV-holding facilities wishing to handle and store WPV2 materials must be fully certified before Phase II.

- *Establish national contingency plans for responding to potential release of or exposure to poliovirus (REF WHO Post-Switch Outbreak Response Plans)*.

- *Request candidate essential poliovirus facilities*[8] *that plan to handle and store infectious WPV materials to be certified against the implementation of 'Containment of WPV2' provisions, including primary and secondary safeguards (Annex 2), as described in Annex 4,* before Phase II. If unable to meet the requirements, all WPV materials must be transferred to a country and facility meeting the requirements or destroyed.

- *Request candidate essential poliovirus facilities*[9] *that plan to handle and store only OPV/Sabin materials (but no WPV), to be certified against the implementation of 'Containment of OPV2/Sabin2' provisions, including primary and secondary safeguards (Annex 3), as described in Annex 4* no later than three months after the switch. If unable to meet the requirements, all OPV/Sabin materials must be transferred to a country and facility meeting the requirements or destroyed.

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

*Preparing for the tOPV-bOPV switch*

- The WHA resolution on the tOPV-bOPV switch will provide details on the process for implementing each step leading to OPV2 withdrawal, recall of unused tOPV, and containment of OPV/Sabin type 2 (OPV2/Sabin2) polioviruses.
    - tOPV-using countries shall respond to the WHA resolution 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.

***Phase II: Poliovirus type 2 containment period***

Phase IIa (*Containment of wild poliovirus type 2 (WPV2)*)

Phase IIa begins when global readiness for OPV2 withdrawal is declared.

As of the beginning of Phase IIa

- *Storage of WPV2 material is no longer permitted in non-essential facilities.*

- *Non-essential laboratory facilities that are likely to handle new WPV2 isolates or new faecal and respiratory samples originating from recent OPV-using countries*
    - *Implement safe and secure working practices* based on risk assessment and appropriate biorisk management systems (CEN, 2011)
    - *Do not retain any WPV2* for long-term storage
    - *Immediately destroy* any newly isolated WPV2 materials, *or transfer* them to an certified essential poliovirus facility after notification of the MoH or other designated national authority and WHO.

- *Certified essential facilities[10] handling and storing WPV2 must implement 'Containment of WPV2' biorisk management standards including primary and secondary safeguards, as described in Annex 2. Facilities that have not yet received formal national certification for 'Containment of WPV2' are no longer permitted to handle and store WPV2 m*aterials in Phase II.

Phase IIb (*Containment of OPV/Sabin type 2 (OPV2/Sabin2) poliovirus*)

Moving forward with the preparations for the tOPV-bOPV switch

[10] Laboratory or IPV production facilities

- *All countries shall notify the general laboratory community of forthcoming requirements for 'Containment of OPV2/Sabin2 polioviruses'.* 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 (REF WHA resolution 2015) pertaining to OPV2/Sabin2 poliovirus destruction or containment will be in force at that time. Communications from the MoH or other designated national authority to all biomedical laboratory facilities shall further encourage destruction of unneeded Sabin materials. Laboratories wishing to maintain access to historic collections of clinical materials potentially infectious for OPV/Sabin polioviruses shall explore options with designated certified essential poliovirus research and reference containment facilities for handling and storage arrangements.

Global tOPV administration for routine immunization will stop (OPV2 cessation) at an effective date established by World Health Assembly.

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 at the time of the WHA resolution (REF) for collection and destruction of tOPV from designated collection points, health facilities or private practitioners, and national and sub-national storage facilities.

  Phase II coincides with a period of intense VDPV surveillance and elimination. Some high risk areas may require the emergency use of monovalent OPV (mOPV2) or trivalent OPV (tOPV) to respond to emerged or re-emerged VDPV2 transmission. In such areas it may be necessary to temporarily suspend '*Containment of OPV2/Sabin2 polioviruses*' until the emergency is resolved.

- *Submit documentation within six months to the Regional Certification Commission that requirements for 'Containment of OPV2/Sabin2 polioviruses' have been met.* The Global Certification Commission will communicate detailed guidelines for assessing and documenting containment through WHO Regional Offices.

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

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

- Storage of OPV2/Sabin2 poliovirus material is no longer permitted in non-essential facilities

- *Non-essential laboratory facilities that are likely to handle new WPV2, aVDPV2, cVDPV2 or cVDPV2 isolates, or new faecal and respiratory samples originating from recent OPV-using countries*

- *Implement safe and secure working practices* based on risk assessment and appropriate biorisk management systems (CEN, 2011)
- *Do 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 an certified essential poliovirus facility after notification of the MoH or other designated national authority and WHO.

- *Certified essential facilities*[11] *handling and storing only OPV2/Sabin2 polioviruses (but no WPV) must implement 'Containment of OPV2/Sabin2 poliovirus' biorisk management standards 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/international certification for '*Containment of OPV2/Sabin2 poliovirus'* are no longer allowed to handle and store OPV2/Sabin2 poliovirus materials.

In preparation for Phase IIIb (see below), countries *with* essential OPV/Sabin facilities shall in addition

- *Implement national and international certification procedures to assess compliance with provisions for 'Final containment of all OPV/Sabin polioviruses', including primary and secondary safeguards.* All nationally certified essential facilities must be certified internationally through WHO (Annex 4). Designated essential Sabin-holding facilities wishing to handle and store any OPV/Sabin poliovirus materials in Phase III must be certified against '*Final containment of all OPV/Sabin polioviruses*' before bOPV cessation. Facilities failing international certification will have to discontinue OPV/Sabin poliovirus activities until international verification of corrected deficiencies. OPV stockpiles are expected to be stored under appropriate containment conditions, based on a risk assessment approved by the competent authority (Annex 3).

- *Request essential poliovirus facilities*[12] *that plan to handle and store infectious Sabin-derived materials (but no WPV) in Phase III, to be certified against the implementation of 'Final containment of all OPV/Sabin polioviruses', including primary and secondary safeguards (Annex 3) as described in Annex 4.* If unable to meet the requirements, all poliovirus materials must be transferred to a country and facility meeting the requirements or destroyed before bOPV cessation.

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

[11] Laboratory or OPV/Sabin-IPV production facilities
[12] Laboratory, Sabin-IPV production, or OPV stockpile facilities

- *Submit documentation to the relevant WHO Regional Certification Commission that requirements for destruction or risk management of WPV materials in Phase II have been met.* The WHO Global Certification Commission will communicate detailed guidelines through WHO Regional Offices for assessing and documenting containment as required for certification of WPV eradication.

In preparation for Phase IIIa (*Enhanced final containment of all wild poliovirus*), countries *with* essential WPV facilities shall in addition

- *Implement national and international certification procedures to assess compliance with provisions for 'Enhanced final containment of all wild poliovirus', including primary, secondary, and tertiary safeguards.* All nationally certified essential WPV-holding facilities wishing to handle and store any WPV materials in Phase III must also be certified internationally through WHO (Annex 4) before Phase III. Facilities failing international certification will have to discontinue WPV activities until international verification of corrected deficiencies.

- *Request essential poliovirus facilities[13] that plan to handle and store infectious WPV materials in Phase III, to be certified against the implementation of 'Enhanced final containment of all wild poliovirus' including primary, secondary and tertiary safeguards (Annex 2) as described in Annex 4.* 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.

***Phase III: Final poliovirus containment***

Phase IIIa (*Enhanced final containment of all wild polioviruses*)

Phase IIIa begins when all 6 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 essential laboratories and IPV production facilities handling and storing WPV materials must

- *Implement 'Enhanced final containment of all wild polioviruses' biorisk management standards for handling and storage of all WPV materials, including primary, secondary and tertiary safeguards, as described in Annex 2.* Facilities that have not yet received formal national and international certification for *Enhanced final containment of all wild polioviruses* are no longer allowed to handle or store WPV materials in Phase III.

Countries *with* essential WPV facilities shall continue to

[13] Laboratories or Salk-IPV production facilities

- *Implement national and international certification procedures to assess compliance of WPV-holding facilities with provisions for 'Enhanced final containment of all wild polioviruses', including primary, secondary, and tertiary safeguards.* All nationally (annually) certified essential facilities must be regularly (e.g. every three years) reassessed internationally through WHO (Annex 4) to renew their certification status. Facilities failing international certification must discontinue WPV activities until international verification of corrected deficiencies.

- *Request essential facilities[14] that handle and store WPV materials in Phase III to be regularly reassessed (annually, with international oversight every three years) against the implementation of 'Enhanced final containment of all wild polioviruses', including primary, secondary and tertiary safeguards (Annex 2) as described in Annex 4, in order to renew 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.

Phase IIIb (*Final containment of all OPV/Sabin polioviruses*)

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

At the effective date, *all* countries must

- *Recall and destroy bOPV stocks.* WHO will provide specific implementation guidelines at the time of the WHA resolution (REF?) for collection and destruction of bOPV from designated collection points, health facilities or private practitioners, and national and sub-national storage facilities.

- *Submit documentation within six months to the Regional Certification Commission that requirements for 'Final containment of all OPV/Sabin polioviruses' have been met.* The Global Certification Commission will communicate detailed guidelines for assessing and documenting containment through WHO Regional Offices.

Phase IIIb begins three months after global bOPV cessation.

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

- *Implement 'Final containment of all OPV/Sabin polioviruses' biorisk management standards for handling and storage of all OPV/Sabin poliovirus materials, including primary and secondary safeguards, as described in Annex 3.* Facilities that have not yet received formal national and international certification for Final *containment* of all *OPV/Sabin polioviruses* are no longer allowed to handle and store OPV/Sabin materials after bOPV cessation.

[14] Laboratory or IPV production facilities

Countries *with* essential OPV/Sabin PV facilities shall continue to

- *Implement national and international certification procedures to assess compliance of* OPV/Sabin-*holding facilities with provisions for 'Final containment of all OPV/Sabin polioviruses', including primary and secondary safeguards.* All nationally (annually) certified essential facilities must be regularly every three years) reassessed internationally through WHO (Annex 4) in order to renew their certification status. Facilities failing international certification must discontinue OPV/Sabin activities until international verification of corrected deficiencies.

- *Request essential poliovirus facilities*[15] *that handle and store* Sabin-derived *materials (but no WPV) to be regularly reassessed against the implementation of 'Final containment of all OPV/Sabin polioviruses', including primary and secondary safeguards (Annex 3) as described in Annex 4, in order to renew 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.

  Facilities finalizing and then housing OPV stockpiles in sealed primary containers must meet international requirements for control, safety, and security as described in the WHO *Standard operating procedures for the stockpile of monovalent oral poliovirus vaccines (mOPV) for the post-eradication/post-OPV era (REF?).* Replenishing OPV vaccine vial stocks from frozen bulk stock after routine OPV use is stopped will have to be done under appropriate containment conditions, based on a risk assessment approved by the competent authority

Table 2: Phased implementation of poliovirus containment

| Pre-requisites | Phase | Begins | Target completion date | Key activities |
|---|---|---|---|---|
| **Phase I: Preparation for containment** | | | | |
| | **I: *Inventory, destruction, preparation for containment of poliovirus type 2*** | Ongoing | Global readiness of OPV2 withdrawal | <u>Inventory, destruction, preparation for poliovirus (PV) containment</u><br>• Survey/inventory of facilities handling or storing infectious or potentially infectious WPV materials<br>*Non-essential facilities*:<br>• Destruction of unneeded PV material<br>• Transfer of needed PV material to essential laboratory facilities |

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

| | | | | |
|---|---|---|---|---|
| | | | | • Adoption of non-retention policy for new WPV/Sabin isolates, to be implemented as of Phase IIa<br><br>*Essential facilities*:<br>• National/international certification |
| **Phase II: Poliovirus type 2 containment period** | | | | |
| **Elimination of circulating WPV2**<br><br>**Elimination of persistent cVDPV2** | **IIa*: Wild poliovirus type 2 containment period*** | Global readiness of OPV2 withdrawal | Global certification of WPV eradication | <u>Containment of WPV type 2 (WPV2)</u><br><br>As soon as global readiness for withdrawal of OPV2 is declared:<br><br>*Certified essential WPV2-holding laboratory and IPV production facilities*:<br>• Handle and store WPV2 materials in 'Containment of WPV2'<br><br>*Non-essential facilities*:<br>• Destroy remaining unneeded Sabin2 material<br>• Transfer needed Sabin2 material to certified essential laboratory facilities<br><br>*Non-essential facilities handling new samples from recent OPV-using countries*:<br>• Implement non-retention policy<br>• Destroy unneeded recently isolated PV material<br>• Transfer needed recently isolated PV material to certified essential facilities |
| **Licensed and available bOPV**<br><br>**Global introduction of IPV**<br><br>**Global tOPV-bOPV switch** | **IIb: *Containment of OPV2/Sabin2 polioviruses (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) | <u>Containment of OPV/Sabin PV type 2 (OPV2/Sabin2)</u><br><br>Within three months of OPV2 withdrawal:<br><br>*Certified essential OPV/Sabin-holding laboratory, or OPV/Sabin-IPV production facilities*:<br>• Handle and store OPV/Sabin materials in 'Containment of OPV2/Sabin2 polioviruses' |
| **Phase III: Final poliovirus containment** | | | | |
| **Three years pass without isolation of WPV** | **IIIa: *Post-eradication*** | Global certification of WPV eradication | Long-term eradication (beyond global bOPV cessation) | <u>Enhanced final containment of all WPV</u><br><br>As soon as eradication is certified:<br><br>*Certified essential WPV-holding laboratory or IPV production facilities*:<br>• Handle and store all WPV materials in 'Enhanced final containment of all WPV' |

| | | | | |
|---|---|---|---|---|
| **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) | <u>Final containment of all OPV/Sabin PV</u><br><br>Within three months of global bOPV cessation:<br><br>*Certified essential OPV/Sabin-holding laboratory or Sabin-IPV production facilities*:<br>• Handle and store OPV/Sabin materials in 'Final containment of all OPV/Sabin polioviruses' |

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# Annexes

# 1. Definitions

The definitions given below apply to the terms as used in this Standard, and may have different meanings in other contexts.

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

***Audit:***. 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 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 provides 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, with access for materials 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.

***Biosafety:*** Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

***Biorisk:*** The 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 the organization's biorisk policy.

***Biosecurity*****:** Laboratory biosecurity describes the protection, control, and accountability for biological agents and toxins within biological facilities to prevent their unauthorized access, loss, theft, misuse, diversion, or intentional unauthorized release.

***CCID$_{50}$:*** Cell culture infectious dose which will infect 50% of the cell monolayers challenged with the defined inoculum.

***Calibration:*** Correlation of the readings of an instrument with a standard.

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

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

- International certification to this Standard is expected to take place every three years under the umbrella of WHO (REF? WHA 2015).

***Containment:*** System for confining microorganisms or organisms or other entities within a defined space.

***Contingency planning:*** Preparing for a future event or circumstances regarded as likely to occur, or as influencing present action.

***Decontamination:*** 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***: 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, essential:*** A facility designated by the Ministry of Health as serving critical national or international functions that involve handling and storage of needed poliovirus infectious materials or potentially infectious materials under conditions set out in this Standard.

***Facility, certifiable****:* A facility approved by the Ministry of Health or other designated national body or authority as a qualified applicant for national and international certification.

***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.

***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, 3rd edition, 2004).

***Guidelines:*** Principles or criteria guiding or directing action.

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

***High efficiency particulate arresting (HEPA) filter:*** A filter capable of removing at least 99.97% of all particles with a mean aerodynamic diameter of 0.3 µm.

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

***Legislation:*** The process of making laws.

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

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

***Penetrations:*** Opening 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 sub-divided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines (OPV)), 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 demonstrate usually 1–15%[16]sequence difference from the parental OPV strain; they may have circulated in the community (cVDPVs) or have replicated for prolonged periods in immunodeficient subjects (iVDPV) or be ambiguous environmental 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 (b).

(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
- Infected animals or samples from such animals, including human poliovirus receptor (PVR) transgenic mice

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

- Derivatives produced in the laboratory that have capsid sequences from wild polioviruses unless demonstrably proven to be more attenuated, less pathogenic, and safer than Sabin strains
- Full-length RNA or cDNA that include capsid sequences derived from wild poliovirus field isolates or clinical specimens, unless viruses derived from them are demonstrably proven to be more attenuated, less pathogenic, and safer than Sabin strains
- 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 in 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 are attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains).

**OPV-like polioviruses:** For the laboratory network not involved in manufacture, OPV like polioviruses are defined as 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 VP1 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 Sabin OPV seeds must be assured and cannot rely on 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 PVR transgenic mice
- Derivatives produced in the laboratory that have capsid sequences from OPV/Sabin strains
- Full-length RNA or cDNA that include capsid sequences derived from OPV/Sabin strains field isolates or from clinical specimens
- 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

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

**Risk:** Combination of the probability of 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.

**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.

**Safeguards, primary:** The 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 an 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 circulation of highly transmissible wild poliovirus in the event of re-introduction.

***Senior Manager (SM):*** The official representative of the institution who has overall authority and accountability for ensuring 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).

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

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

***Validation:*** The documented act of proving that a procedure, process, equipment, material activity, or system actually leads to expected results.

***Verification:*** Establish truth or correctness through demonstration (or documentation).

***WHO Global Certification Commission (GCC):*** The term commonly used to refer to the *WHO 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, WHO certifying that global polio eradication has been achieved.

***WHO Regional Certification Commission (RCC):*** The term commonly used to refer to the *WHO 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.

***WHO National Certification Commission (NCC):*** The term commonly used to refer to the *WHO National Commission for the Certification of the Eradication of Poliomyelitis,* which has been established in country with responsibility to certify to the RCC that eradication has been achieved throughout the country.

# 2. Biorisk management standard for essential poliovirus facilities holding wild poliovirus



## *Introduction*

A facility-associated poliovirus infection or release into the environment during the Endgame 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 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; design and operation of the containment facility; practices and procedures; 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 an essential containment facility and consist of a national routine childhood immunization policy and demonstrated high (=DPT3; >90%) national population coverage (World Health Organization, 2006). *Tertiary safeguards* of facility location minimize the risk of transmissible poliovirus by placement of 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 essential facilities handling and storing WPV2 at *Readiness for tOPV withdrawal*. Primary, secondary, and tertiary safeguards are

required for essential facilities handling and storing any WPV materials in the *final containment phase*.

This *Biorisk management standard for essential poliovirus facilities holding WPV materials* describes the international requirements for primary safeguards established for essential poliovirus laboratory handling and storing WPV or Salk-IPV production facilities (Annex 2). The *Standard* is based on *CWA15793, Laboratory Biorisk Management* (CEN, 2011), the principles of the WHO *Laboratory Biosafety Manual* (3rd Edition, 2004) and the extensive poliovirus scientific literature spanning nearly 7 decades (Dowdle WR et al., 2006). The *Standard* serves as the framework for national and international certification (Annex 4: *International certification of essential poliovirus facilities* in the Endgame period and in the post-eradication/post-OPV era*)*. It consists of 16 elements and sub elements 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. The *Standard* further assumes that essential facility personnel and management at all levels fully appreciate the enormity of the consequences of accidental or deliberate 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 (Dowdle WR and Birmingham ME, 1997). Infectivity is inactivated by dehydration, heat (>50 °C), or treatment with dilute solutions of formaldehyde or bleach at appropriate concentrations.

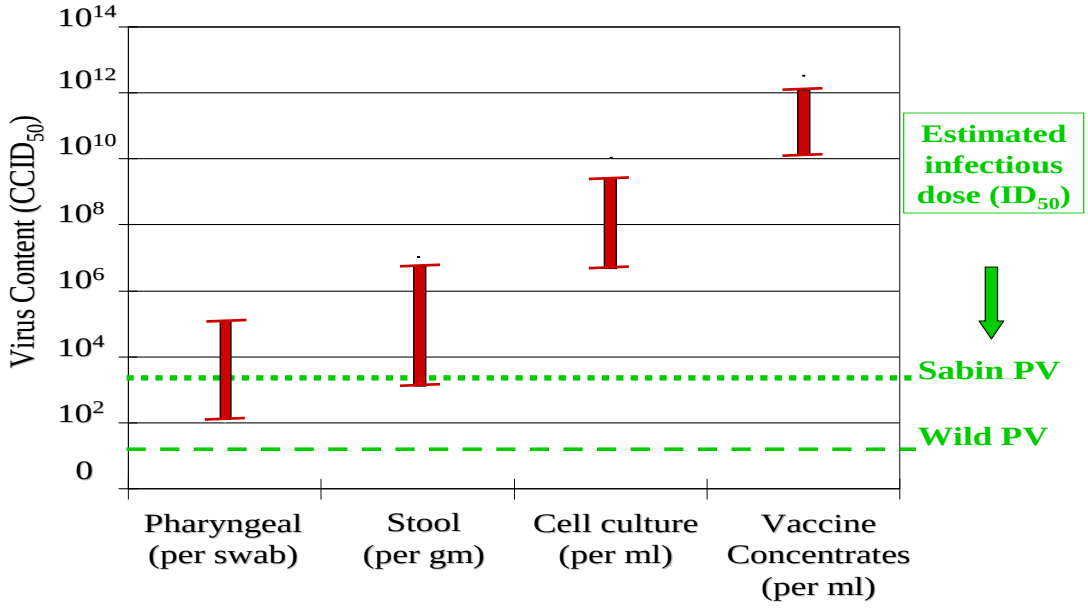
The most common routes of exposure to infectious agents in the facility environment are: 1) ingestion, 2) inhalation, 3) injection, and 4) contaminated skin and mucous membranes. The infectious dose is a factor of virus virulence, route of presentation, and virus particles in sufficient number to overcome mechanical loss and natural and immune host defenses. In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/gm (Sabin) to $10^{4.3}$ $CCID_{50}$/gm (wild) in stool samples, to$10^{8}$ $CCID_{50}$/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 or re-infection of the gut (REF?). Ingestion of poliovirus may result from any laboratory operation, activity, or incident that leads to 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 ingestion of sufficient poliovirus particles. Droplets created by sprays, spills, and splash of poliovirus cell cultures ($10^8$ $CCID_{50}$) and concentrates ($10^{11}$ $CCID_{50}$) constitute the highest personnel exposure risks (Figure 2).

Inhalation, defined as exposure to small particle aerosols <5 µm (droplet nuclei) deposited predominately in the lower respiratory tract, has been identified as a possible route of infection for poliovirus (REF?). 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 infection through mucociliary transport to the pharyngeal region. Inhalation risks may be further reduced in facility environments maintained at low relative humidity (<50%) (REF?). Antibodies acquired through immunization greatly reduce infection risks through injection or breaks in skin or mucous membranes.

Figure 2: 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) release of contaminated air, 3) contaminated effluents and waste water recovered form secondary sewage treatment plants, 4) uncontrolled transport of infectious material, 5) solid waste transported to landfills, 6) contaminated equipment or materials removed from the facility, 7) escape of infected animals, and 8) a deliberate theft or release of infectious agents from a facility. Exposure risks through the latter four routes (4-7) are low for poliovirus facilities that adhere to international regulations for the transport of infectious substances, Good Laboratory Practice, and Good Manufacturing Practice and likely low for inhalation of contaminated air effluent

[17] Estimated ingestion 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 ingestion of sufficient poliovirus particles.

where facilities maintain low relative humidity environments and exhaust air away from direct human exposure. Exposure risks through ingestion of effluents range between high and low, depending on poliovirus content of facility effluent, sewerage system size and integrity, and potential for human consumption. Risks of community exposure are highest through facility personnel unknowingly contaminated or infected with poliovirus. Routine IPV immunization of facility personnel may greatly reduce the risk of intra- and extra-household transmission.

Effective poliovirus risk management is achieved by careful assessment of exposure risks, 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 infection of laboratory workers by ingestion. Airborne transmission is conceivable but not demonstrated and infection through parenteral exposure such as needle stick is unlikely in immunized individuals.

***Management system elements***

| *Biorisk management standard for essential poliovirus facilities holding WPV materials* | | | | |
|---|---|---|---|---|
| ***CWA 15793 Clause No[18]*** | ***Biorisk Management Element No*** | ***Requirements for Containment of WPV2*** | ***Requirements for Enhanced final containment of all WPV*** | ***Guidance*** |
| | | **Element 1 – Biorisk Management System**<br><br>The Biorisk Management System element examines the system and policy in place to manage the laboratory biorisk. Effective management and organization are vital to the success of any activity, and management commitment and leadership lays 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 towards managing risk will be ineffective. The way management thinks and acts, has a major impact on performance.<br><br>**Sub-elements**<br>1.1. Biorisk Management Policy<br>1.2. Objectives, Targets and Programme<br>1.3. Roles, Responsibilities and Authorities<br>1.4. Records, Document and Data Control<br>1.5. Analysis of Data<br>1.6. Change Management<br>1.7. Consultation and Communication<br>1.8. Programme of Work<br>1.9. Work Planning and Capacity<br>1.10. Legal Requirements<br>1.11. Continual Improvement<br>1.12. Preventive Action<br>1.13. Control of Non-Conformities<br>1.14. Inspection and Audit | | |

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

| *Biorisk management standard for essential poliovirus facilities holding WPV materials* | | | | |
|---|---|---|---|---|
| ***CWA 15793 Clause No[18]*** | ***Biorisk Management Element No*** | ***Requirements for Containment of WPV2*** | ***Requirements for Enhanced final containment of all WPV*** | ***Guidance*** |
| | | 1.15. Corrective Action<br>1.16. Contractors and Suppliers<br>1.17. Biorisk Management Review<br>1.18. Biorisk Management System | | |
| | 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:<br>1. Development<br>2. Authorization<br>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:<br>1. The overall biorisk management objectives<br>2. A commitment to improving biorisk management performance | | The policy should require all projects/work areas to be assessed for risks and a full assessment prepared before work is approved to commence. |
| **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:<br>1. Protecting staff, contractors, visitors, community and environment from poliovirus materials that are stored or handled within the facility<br>2. Reducing the risk of unintentional release of, or exposure to poliovirus materials | | Including the need to conduct risk assessments and implement the required control measures. |

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| | | 3. Reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials<br>4. Complying with all legal requirements applicable to the poliovirus materials that will be handled or possessed, and with the requirements of this standard<br>5. Ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements<br>6. Effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups<br>7. Continually improving biorisk management performance | | |
| | 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:<br>1. Established<br>2. Implemented<br>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 investigation of incidents and accidents and improving controls and their implementation and by ensuring that adequate resources are provided to maintain the effectiveness of the controls.<br><br>Note: Refer to Element 2 – Risk Assessment. |
| | 1.3. | **Roles, Responsibilities and Authorities** | | |

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| **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 management of biorisk rests with top management but tasks may be delegated through the organization provided that 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 the standard. It is important to define roles and responsibilities and that there is clear communication within the Organization in terms of the actions that need to be taken, and who has the required authority. |
| **CWA 4.4.1.1** | 1.3.2. | Top management ensures that roles, responsibilities and authorities 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.<br><br>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 the titles 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 |

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| | | | | resources. |
| **CWA 4.4.1.2** | 1.3.4. | A senior manager has been designated with operational responsibility for overseeing the system for management of biorisk. | | 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. | Functions of the senior manager for the management of biorisk include:<br>1. Providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility<br>2. Reporting to top management on the performance of the biorisk management system and any need for improvement<br>3. Ensuring promotion of the biorisk management system throughout the organization<br>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 biorisk management needs of the facility (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 and may be either a dedicated function, or the role can be addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management advisor(s), security manager and the occupational health professional. Dependent on the nature of the agenda or nature of the work others may be included e.g. the facility manager and /or worker and community |

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| | | | | representatives. |
| **CWA 4.4.1.3** | 1.3.7. | The biorisk management committee reports to senior management, and:<br>1. Has documented terms of reference<br>2. Includes a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken<br>3. Ensures issues addressed are formally recorded, actions allocated, tracked and closed out effectively<br>4. Is chaired by a senior individual<br>5. Meets at a defined and appropriate frequency, and when otherwise required | | Functions of the committee should include:<br>a. contributing to the development of institutional biorisk policies and codes of practice;<br>b. approving proposals for new work or significant modifications to the potential risk associated with existing activities;<br>c. reviewing and approving protocols and risk assessments for work involving polioviruses;<br>d. reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs.<br><br>The list of roles for the biorisk management committee is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed. |
| **CWA 4.4.1.4** | 1.3.8. | A competent individual(s) is 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 (BSO) or biological safety advisor. This function should normally be regarded as an advisory position and not directly responsible for managing biorisk, as this rests with those conducting and managing the work within the organization (e.g. |

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| | | | | scientific director, principal investigator, department head, laboratory manager, group leader, etc.). The role and knowledge of the biorisk advisor is important to develop, implement, maintain and continually improve a biosafety and biosecurity programme based on a management system. The advisor should be competent to perform the role, and allocated sufficient time and other resources to do the job effectively. |
| **CWA 4.4.1.4** | 1.3.9. | The Biorisk management advisor role is independent of those responsible for implementing the programme of work. | | In the execution of his/her biorisk management duties the advisor 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 advisor:<br>1. Reports directly to the responsible senior manager<br>2. Has delegated authority to stop work in the event that it is considered necessary to do so | | Functions of the biorisk management advisor should include:<br>a. verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed;<br>b. advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / biorisk management committee;<br>c. ensuring that relevant and up-to-date |

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| | | | | information and advice on biorisk management is made available to scientific and other personnel as necessary;<br>d. advising on biorisk management issues within the Organization (e.g. management, biorisk management committee, occupational health department, security);<br>e. contributing to the development and / or delivery of biorisk training activities;<br>f. ensuring that all relevant activities are performed in compliance with biorisk regulations and that required biorisk authorizations for work are in place.<br><br>The list of roles for the biorisk management advisor is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed. |
| **CWA 4.4.1.5** | 1.3.11. | An individual(s) with responsibility for the scientific programme within the facility has been designated with responsibilities relevant to biorisk management. | | The scientific manager is the individual 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. adherence 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 |

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| | | | | facility and be in a supervisory / management position and may be referred to as Head of Department, Principal Investigator, Laboratory Supervisor / Manager or Group Leader. Competence will be required in technical / scientific aspects of the poliovirus materials being used and their control, together with 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 so as to avoid any omissions and ensure consistency. |
| **CWA 4.4.1.5** | 1.3.12. | The scientific management functions include:<br>1. Ensuring that all work is conducted in accordance with established policies and guidelines described in this standard<br>2. Supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility<br>3. Planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available<br>4. Ensuring required authorizations for work are in place<br>5. Ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place<br>6. Ensuring that 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 |

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| | | | | occupational health nurse with understanding of the poliovirus materials that are handled within the facility.<br><br>The role should include providing input into risk assessment from a worker health perspective, advising on first aid / emergency treatment measures and follow-up, liaising with external healthcare providers, and coordinating medical examinations, surveillance and vaccination programmes.<br><br>Roles and responsibilities of the occupational health professional 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 activities and risks of the facility. | | |
| CWA 4.4.1.7 | 1.3.15. | A facilities manager(s) has been appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this Polio Biorisk Management Standard. | | The facilities manager would normally be an engineer or someone 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. Roles and responsibilities of the facilities management personnel should be determined in light of requirements set out |

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| | | | | in this standard. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined so as to avoid any omissions and ensure consistency. |
| **CWA 4.4.1.8** | 1.3.16. | A security manager has been designated with responsibilities determined in accordance with requirements set out in this Polio Biorisk Management Standard. | | The security manager would normally be someone with an in-depth knowledge of laboratory and facility security, who should liaise with other personnel (e.g., biorisk management advisor) 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. Roles and responsibilities of the security personnel 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 maintained, an animal care manager has been designated with responsibilities determined in accordance with requirements set out in this Polio Biorisk Management Standard. | | The animal care manager would normally be someone with 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 advisor, occupational health professional, etc.) to implement effective and proportionate laboratory biosafety and laboratory biosecurity measures. A qualified veterinarian should be available for additional advice. The role should include providing input into risk assessment and |

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| | | | | management from an animal care and use perspective. |
| | 1.4. | **Records, Document 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 upon 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.<br><br>Documented records shall be maintained in paper or electronic form for a minimum period of 10 years from the day of withdrawal and be available in English for review during national/international certification procedures. | | Controlled documents may include:<br>a. risk assessments, standard operating procedures (SOPs) and safety manuals;<br>b. job hazard analyses and charts of authority;<br>c. design records and commissioning / test plans, maintenance plans and records and all associated data;<br>d. audit and inspection checklists;<br>e. laboratory biosecurity manuals and risk assessments, authorizations and other security documents;<br>f. training records;<br>g. containment equipment certifications.<br><br>The list of controlled documents is neither exhaustive nor comprehensive 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 |

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| | | | | should be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records. A procedure should be established to define the controls needed to approve documents prior to issue or public release to ensure sensitive information such as specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls for review, update and re-approval of documents, and for the change control and revision process. |
| | 1.5. | **Analysis of Data** | | |
| **CWA 4.5.1** | 1.5.1. | Appropriate data are determined, collected and analyzed 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 the 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. | | The changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include |

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| | | | | evaluation of the effect of the changes on the risk assessment.<br><br>The following are examples of changes that should be subject to the change management process:<br>a. modifications to buildings and equipment or their operation, which may or would have an effect on biorisk;<br>b. introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel);<br>c. changes to the programme of work, including alterations to work flow or volume which may or would have an effect on biorisk;<br>d. alterations to SOPs, including significant changes in materials or reagents;<br>e. modifications to entry / exit protocols;<br>f. modifications to personnel policies and visitor protocols;<br>g. modifications to disinfection, decontamination and other waste management methodologies;<br>h. changes associated with PPE provision and usage. |
| | 1.7. | **Consultation and Communication** | | |

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| CWA 4.4.4.3 | 1.7.1. | Relevant biorisk information relating to the organizations activities is communicated to and from employees and other relevant parties. | | The organization should implement mechanisms to ensure that relevant and current information with the potential to affect workers and others is defined and delivered effectively at appropriate intervals. In the workplace this could mean regular team meetings and briefings, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others including:<br>a. local, national and international governmental Organizations;<br>b. relevant regulatory agencies;<br>c. certifiers;<br>d. emergency services and healthcare providers;<br>e. contractors and suppliers (e.g. cleaners, maintenance providers, security personnel);<br>f. local community representatives (e.g. through a community liaison committee).<br><br>Systems should be set in place to identify existing or emerging technologies or other relevant information relating to the containment of the poliovirus materials being handled or stored, and that this information is shared with relevant staff through the use of appropriate media. This may include circulation of appropriate signage, documents, team briefings and |

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| | | | | 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 pertaining to the biorisks of the organization. | | |
| | 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 of work 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, etc). All activities associated with the work programme should be specified and supported by formal SOPs approved in accordance 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. | There is sufficient resource capacity and capability 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 |

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| | | | | |
| | 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 regulatory requirements with which the organization shall comply. | | The organization should adopt measures to identify legal and other requirements for the facility in relation to the poliovirus materials that will be held and used, but also other regulations including for example: worker protection and rights, environmental impact and general health & safety (e.g. fire, electrical, etc.). There is a need to monitor for new and upcoming requirements, as well as those already in existence. This information should be kept up to date and the requirements incorporated into the biorisk management system of the facility. |
| | 1.11. | **Continual Improvement** | | |
| **CWA 4.1.2** | 1.11.1. | The organization continually improves the effectiveness of the biorisk management system through the use of:<br>• the policy,<br>• objectives,<br>• self-audit programme,<br>• audit results,<br>• analysis of data,<br>• risk assessment,<br>• corrective and preventive actions and<br>• the management review. | | The organization should strive to continue to develop and refine the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved through objective setting and targets placed upon those working within the facility, and monitoring progress to ensure the objectives are achieved. |

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| | 1.12. | **Preventive Action** | | |
| **CWA 4.5.4.4** | 1.12.1. | Action is taken to identify and eliminate the causes of potential nonconformities in order to prevent their occurrence. | | A procedure should be established to define requirements for:<br>a. determining the potential non-conformities and their causes;<br>b. evaluating the need for action to prevent<br>c. occurrence of non-conformities;<br>d. determining and implementing action needed;<br>e. recording of the results of action taken;<br>f. reviewing 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 Non-Conformities** | | |
| **CWA 4.5.4.2** | 1.13.1. | Situations that do not conform to the requirements of the Laboratory Biorisk Management Standard are identified and controlled to prevent undesirable consequences. | | The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure. |
| **CWA 4.5.4.2** | 1.13.2. | Records of the nature of the non-conformity and any subsequent action taken are maintained. | | |
| | 1.14. | **Inspection and Audit** | | |
| **CWA 4.5.5** | 1.14.1. | A programme of inspection and audit is conducted which is appropriate to the risk associated with the facility. | | Inspections may be frequent checks on specific areas conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels / concentrations |

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| | | | | and air exchange rates / maintenance of directional air flow), or 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, not just in time for scheduled inspections. Audits should be performed by competent individuals who are independent of the activity being audited. Records should be maintained of findings of inspections / audits, including action taken to close out any non-conformities or 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 to the requirements of this Polio Biorisk Management Standard, and that it is effectively implemented and maintained.<br><br>*National inspection and audit.* A program of unannounced inspection and audit shall be conducted, no less than annually, by national authorities to determine if the biorisk management system conforms to the requirements of this standard and is functioning properly and that necessary corrective actions are taken and verified without undue delay.<br><br>*International inspection and audit.* Top management shall ensure that information and access necessary for the periodic comprehensive international review of the poliovirus facility is made available in English as requested by the international review team (REF WHA 2015?) 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 routine OPV use (GAPIII)*, | | |

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| | | 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 non-conformities and their causes. | | |
| **CWA 4.5.5** | 1.14.4. | Follow-up activities arising include:<br>1. The verification of the actions taken<br>2. Reporting of verification results | | |
| | 1.15. | **Corrective Action** | | |
| **CWA 4.5.4.3** | 1.15.1. | Action is taken to eliminate the causes of non-conformities with the requirements of this *Biorisk management standard for essential poliovirus facilities holding WPV materials (BRM WPV)* in order to prevent recurrence. | | A procedure should be established to define requirements for:<br>a. reviewing the non-conformities;<br>b. determining the cause of non-conformities;<br>c. evaluating the need for action to ensure that non-conformities do not recur;<br>d. determining and implementing action needed;<br>e. recording results of action taken;<br>f. reviewing 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 potential impact on the biorisk involved. | | |

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| **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 impact on biorisk, there are many that may. Suppliers that should be considered include, but are not limited to, those that provide:<br>a. cleaning services;<br>b. laboratory equipment;<br>c. waste management or disposal services;<br>d. IT support services;<br>e. equipment and facility maintenance services;<br>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 of the results of evaluations and any necessary actions arising from the evaluation are maintained. | | |
| | 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 at a defined frequency determined by the needs of the organization, but at least annually. |
| **CWA 4.6.1** | 1.17.2. | The review includes:<br>1. Assessing opportunities for improvement<br>The need for changes to the system, procedures, policies and objectives | | The review input should include information on:<br>a. results of audits;<br>b. compliance to SOPs and work instructions;<br>c. status of risk assessment activities; |

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| | | | | d. status of preventive and corrective actions;<br>e. follow-up actions from previous management reviews;<br>f. changes that could affect the system;<br>g. recommendations for improvement;<br>h. results of accident / incident investigations. |
| **CWA 4.6.1** | 1.17.3. | Records from the management review are maintained. | | The review output should include decisions and actions related to:<br>i improvement of the effectiveness of the biorisk management system;<br>ii improvement related to the requirements and risk assessments;<br>iii 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 in accordance with the requirements of this Polio Biorisk Management Standard. | | |
| | | **Element 2 - Risk Assessment**<br><br>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.<br><br>**Sub-elements** | | |

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| | | 2.1. Process, Methodologies and Procedures<br>2.2. Assessment Timing and Scope<br>2.3. Roles and Responsibilities<br>2.4. Hazard Identification<br>2.5. Risk Assessment<br>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 in accordance with this Polio Biorisk Management Standard. | | |
| **CWA 4.3.1.1** | 2.1.2. | The performance of the risk management system 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 that are 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 with respect to its scope, nature and timing so that it is proactive rather than reactive. | | The following should trigger either a new risk assessment or review of an existing one:<br>a. commencement of new work or changes to the programme of work including the introduction of new biological agents or alterations to work |

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| | | | | flow or volume;<br>b. new construction / modifications to laboratories, plant and equipment or its operation;<br>c. introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel);<br>d. significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, PPE provision / usage entry / exit protocols, etc.);<br>e. when unexpected events that may have relevance for the management of biorisks are observed;<br>f. when actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure);<br>g. when considering emergency response and contingency planning requirements;<br>h. as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).<br><br>There are many defined methodologies and approaches available for conducting hazard |

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| | | | | identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required. One framework which organizations may consider adopting is outlined in Figure 1 of CWA 15793:2011 (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 the assignment of trained personnel for management, performance of work, 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 do one of the following:<br>a. initiate action to prevent or reduce the adverse effects of risk;<br>b. control further treatment of risks until the level of risk becomes acceptable;<br>c. identify and record any problems relating to the management of risks;<br>d. initiate, recommend or provide solutions through designated channels;<br>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:<br>1. Identified<br>2. Documented | | The first stage in the risk management process is to identify all hazards that are relevant for biorisk. It is useful to involve the |

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| | | | | whole work team in this process and to use inputs from organizational experts on safety and risk management.<br><br>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 will include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.<br><br>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.<br><br>A hazard identification exercise should use information including:<br>a. group experience and knowledge;<br>b. external or specialized expertise not found in the facility;<br>c. results of previous assessments;<br>d. surveys of previous |

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| | | | | accidents/incidents;<br>e. hazardous materials data;<br>f. information on hazardous organisms;<br>g. guidelines and codes of practice;<br>h. facility drawings;<br>i. SOPs, manuals, etc.;<br>j. process maps.<br><br>Defined methodologies and approaches are available for conducting hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and associated activities. Hazard identification should be appropriate in nature, 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:<br>1. Identified<br>2. Implemented<br>3. Maintained | | The risk assessment should categorize risks to identify those which 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 through the use of a risk matrix identifying likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be |

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| | | | | relevant and appropriate.<br><br>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 made of the inherent risk from polioviruses(e.g. from risk grouping descriptions, material safety data sheets etc.). After definition and implementation of control measures the risks should be reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented. |
| | 2.6. | **Risk Control** | | |
| **CWA 4.3.1.5.** | 2.6.1. | Suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are:<br>1. Identified<br>2. Implemented<br>3. Maintained | | The risk management approach should include a control plan to include:<br>a. who is responsible and accountable for implementation of the plan;<br>b. what resources are to be utilized (e.g. people, budget);<br>c. timetable for implementation;<br>d. details of the mechanism and frequency of review of compliance with the plan.<br><br>Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an |

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| | | | | alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls, or the reliance on personal protective equipment (PPE). |
| | | **Element 3 – Poliovirus Inventory and Information**<br><br>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 will depend upon the pathogens being held, and will range in complexity from simple lists to secure databases. This element also examines the way materials are stored, including segregation, labeling systems, and controlling stocks of cultures.<br><br>**Sub-elements**<br>3.1. Inventory<br>3.2. Information and Records<br>3.3. Transfer of Poliovirus Materials<br>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:<br>a. identifying all poliovirus materials held, including cultures, specimens and other sources (e.g. infected tissues / samples or animals);<br>b. storing poliovirus material within the containment perimeter of the poliovirus |

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| | | | | 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;<br>c. ensuring movement of poliovirus materials to and from storage meets the standards of element 15 (Transport Procedures);<br>d. ensuring the surfaces of all storage vessels are decontaminated with a validated method for inactivating polioviruses<br>e. restricting access to poliovirus materials to authorized individuals with a demonstrable legitimate need;<br>f. implementing effective physical security measures according to risk (e.g. locks, alarms, access controls, etc.);<br>g. developing and maintaining a reliable sample identification system;<br>h. segregating and storing poliovirus materials according to risk;<br>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 those materials. |

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| | 3.2. | **Information and Records** | | |
| **CWA 4.4.4.2** | 3.2.1. | Records relating to the poliovirus inventory are:<br>1. Current<br>2. Complete<br>3. Stored securely with adequate backup provision | | Inventory information should include:<br>a. the name(s) of and contact information for the individuals(s) responsible for the poliovirus material and details of other personnel with access to the poliovirus materials or immediate area based on the level of the risk;<br>b. restricted access to the detailed inventory records to those individuals whose work requires access to that information;<br>c. legible and robust identification numbers and other relevant identifiers;<br>d. records of quantities / volumes of poliovirus materials (number of containers / vials or applicable equivalent),exact location of storage, and ability to account for materials at all times;<br>e. origin, including geographical source and date of collection<br>f. records of materials removed from storage to conduct work and the fate of those materials and any newly developed stocks following the completion of the work (consumed, destroyed, removed from the facility returned to storage in X location) . |

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| | 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 the risk. | | Controls should be set in place to ensure that all the necessary checks and documented assurances are received to ensure 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 high risk, more stringent controls including shipment tracking and verification of receipt are important considerations |
| | 3.4. | **Monitoring and Control** | | |
| **CWA 4.5.3** | 3.4.1. | A review of the inventory is conducted 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 upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse. Poliovirus inventories shall be monitored such 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. An inventory review shall be conducted at least annually. |
| **CWA 4.5.3** | 3.4.2. | Measures are put in place to minimize the quantities of poliovirus materials that make up the inventory. | | The organization should demonstrate proactive measures towards the reduction of risk through elimination, substitution or |

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| | | | | minimization of volumes / quantities of poliovirus materials used, and the number of manipulations conducted. Procedures should be in place to investigate potentially missing biological agents appropriate for the level of risk. |
| | | **Element 4 – General Safety**<br><br>The General Safety element examines the processes in place to make sure hazards associated with personnel's work in the facility are identified and managed while addressing their implications on biorisk. Both preventive and proactive approach should be taken to establish measures to identify, detect, mitigate, and respond to emergencies due to general safety such as fire, electrical, radiation, chemical, animal care, and pressurized equipment.<br><br>**Sub-elements**<br>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 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 |

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| | | | | respond to emergencies, taking into consideration potential implications for poliovirus control in such measures. Issues addressed should include but are not limited to:<br>a. general laboratory safety;<br>b. fire safety;<br>c. electrical safety;<br>d. radiation safety;<br>e. chemical safety;<br>f. use of gasses (including risk of asphyxiation);<br>g. hot work and cold work;<br>h. equipment under pressure;<br>i. laboratory animal care and use;<br>j. general housekeeping, including storage requirements and tidiness and control of general waste. |
| | | **Element 5 – Personnel and Competency**<br><br>The Personnel and Competency element looks at the processes in place to make sure that people with appropriate qualifications and backgrounds are recruited, that they are subsequently trained in all aspects of the work programme and their competency assessed and monitored in a structured way. Other issues addressed include the way in which capacity issues are addressed and how staff turnover is managed to ensure the organisation is not left vulnerable when critical roles are vacated.<br><br>**Sub-elements**<br>5.1. Recruitment<br>5.2. Training<br>5.3. Competence | | |

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| | | 5.4. Continuity and Succession Planning<br>5.5. Exclusion | | |
| | 5. | **PERSONNEL AND COMPETENCY** | | |
| | 5.1. | **Recruitment** | | |
| **CWA 4.4.2.1** | 5.1.1. | Qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process. | | Prior to taking up an appointment the organization should ensure that:<br>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, etc.);<br>b. appropriate controls are implemented if existing employees are transferred to areas where there may be an increased risk profile;<br>c. all personnel who will be entering areas with potential for exposure to poliovirus materials accept compliance with the healthcare standards outlined in element 9 (Healthcare), specifically including immunization with IPV every 3 years and an annual medical examination including determination of poliovirus antibody titres.<br>d. an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students, etc.), and measures implemented to ensure they are applied |

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| | | | | 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 address:<br>a. definition of biorisk training needs, including training specific to characteristics of poliovirus and the procedures for minimizing risk within the facility, for all persons working within the containment perimeter as well as all persons who may have a need to enter the perimeter, including medical support staff, maintenance staff and emergency responders;<br>b. provision of required biorisk training;<br>c. determination of effectiveness of biorisk training;<br>d. provision of refresher biorisk training;<br>e. restrictions on personnel to ensure they do not perform tasks for which they are not trained;<br>f. maintenance of adequate records<br><br>Training should include raising personnel awareness of biorisk issues including the relevance of human factors in biorisk management. |
| | 5.3. | **Competence** | | |

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| CWA 4.4.2 | 5.3.1. | Personnel that 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.<br>Procedures should address:<br>a. definition of competency needs;<br>b. demonstration of successful completion of required training;<br>c. demonstration of ability to perform tasks under supervision and unsupervised;<br>d. restrictions on personnel who have not demonstrated competence to ensure they do not perform tasks for which they are not eligible;<br>e. maintenance of adequate records.<br><br>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:<br>1. Education<br>2. Training<br>3. Experience | | |
| CWA 4.4.2 | 5.3.3. | The organization has defined required competency levels. | | |
| CWA 4.4.2 | 5.3.4 | Records are maintained verifying that staff members have attained and demonstrated those levels of competency | | |

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| **CWA 4.4.2** | 5.3.5. | Personnel that conduct activities within the facility are under close supervision until competency has been demonstrated. | | |
| | 5.4. | **Continuity and Succession Planning** | | |
| **CWA 4.4.2.3** | 5.4.1. | Adequate back-up and contingency measures are in place to address the need for continuity and succession planning. | | The Organization should identify roles and individuals and ensure that 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 ensure 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 their departure or unavailability. |
| | 5.5. | **Exclusion** | | |
| **CWA 4.4.4.7.3** | 5.5.1. | Measures are set 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 procedures should address:<br>a. removal of access to the facility (e.g. removal of passes, changes of keys, access codes and other security devices, etc.);<br>b. removal of access to information relating to the facility including documentation, computerized records and data;<br>c. immediate physical removal of |

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| | | | | personnel if deemed necessary. |
| | | **Element 6 – Good Microbiological Technique**<br><br>The Good Microbiological Techniques element examines how an organization identifies appropriate microbiological techniques and controls, and how these are then implemented and reviewed. A major part of this 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.<br><br>**Sub-elements**<br>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 can be adhered to effectively. | | As appropriate, procedures should address risks associated with but not limited to the following:<br>a. handling of infectious poliovirus materials<br>b. animal handling;<br>c. centrifugation;<br>d. control of needles and sharps;<br>e. correct use of vacuum pumps;<br>f. culture, purification and storage techniques;<br>g. minimization / containment of aerosols; |

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| | | | | h. pipetting;<br>i. sonication and other mechanical forms of cell / tissue disruption;<br>j. use of biological safety cabinets;<br>k. use of disinfectants, including spill control, routine decontamination, hand washing and showering;<br><br>This list is neither exhaustive nor comprehensive 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:<br>a. required use of devices, e.g. BSCs , which are validated to maintain primary containment for all procedures using live poliovirus<br>b. 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)**<br><br>The Clothing and PPE element examines how an organization ensures that staff is | | |

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| | | provided with the right tools to minimize potential exposures, and to make sure that they know how and when to use them. This element specifically addresses characteristics of some key items, for example use of respirators and positive pressure suits, but considers other commonly used items including gloves, laboratory coats and footwear.<br><br>**Sub-elements**<br>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:<br>a. ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback, etc.);<br>b. ensuring all personnel who have to use PPE (including scientific staff, visitors and contractors) are identified and supplied with correct fitting equipment and clothing;<br>c. explicitly addressing selection and use of PPE in SOPs, training and competency assessments;<br>d. defining and conducting an appropriate programme to ensure that routine checks and maintenance of PPE are defined and carried out;<br>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);<br>g. providing adequate PPE for use during both normal and emergency working conditions;<br>h. ensuring procedures are in place for the cleaning and if appropriate the validated decontamination of used PPE including the safe storage prior to decontamination.<br><br>Personal protective equipment 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 manufacturers specifications. PPE should be made available by the employer at no cost to the employee. |
| 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 on the basis of a risk assessment and may include the use of face shields, goggles, gloves, masks, HEPA-filtered respirators, clothing strictly dedicated for use within the containment perimeter, including solid front gowns or other clothing protecting the body from exposure. |

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| | | **Element 8 – Human Factors**<br><br>The Human Factors element is critical in any biorisk management programme, addressing issues as diverse as raising awareness of biorisk issues, through initiating change management and how to measure and improve the biorisk culture within an organization. Creating an environment where people are confident in reporting what has gone wrong and eliminating blame culture are also addressed.<br><br>**Sub-elements**<br>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 behavior, including the management of how workers interact with the facility and its equipment. | | The Organization should ensure that factors associated with behaviors, 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 behavior 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.<br><br>Measures should be set in place to |

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| | | | | address:<br>a. human reliability and behavioral safety, including adherence to procedures;<br>b. team building and motivation;<br>c. communication, consultation and feedback;<br>d. conflict management and resolution;<br>e. management of stress and fatigue;<br>f. empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified;<br>g. access to counselling<br>h. avoidance of "blame culture", including willingness to report accidents, incidents or unsafe conditions / behaviours, and protection of workers who do so;<br>i. ergonomics, including equipment and work practice design to take account of individual needs;<br>j. respect for individual privacy and dignity. |
| | | **Element 9 – Healthcare**<br><br>The Healthcare 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.<br><br>**Sub-elements** | | |

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| | | 9.1. Worker Health Programme<br>9.2. Vaccination of Personnel<br>9.3. Medical Emergencies | | |
| | 9. | **HEALTHCARE** | | |
| | 9.1 | **Worker Health Programme** | | |
| **CWA 4.4.4.6** | 9.1.1. | The organization ensures that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to poliovirus materials, is managed effectively including prevention and protection measures. | | The programme should address the needs of all individuals who may be associated with the facility, including providing assurance that contractors and visitors receive the required level of protection in line with the activities they will 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 involving all relevant personnel. | | Relevant personnel that may be consulted by the programme include:<br>a. the biorisk management advisor;<br>b. the occupational health professional;<br>c. facility personnel and employee representatives;<br>d. external experts, including emergency responders;<br>e. biorisk management committee members;<br>f. veterinary and animal care facility staff;<br>g. human resources representatives;<br>h. communicable disease specialist;<br>i. scientific management.<br><br>Personnel considered to have significant |

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| | | | | risk of exposure should be identified and their healthcare needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation / testing in the event of exposure. The health including the immune status of the individual, including an assessment of polio antibody titres as described in section 9.2.3. should be considered and periodic checks as appropriate to work conditions should be established.<br><br>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 use appropriate PPE safely, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status, substance abuse, etc.).<br><br>Information covered by the worker health programme should be treated in confidence. All individuals should have access to healthcare consultation either with a corporate or institutional |

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| | | | | occupational health facility or an independent health care provider, and be informed as to the nature of any treatments / vaccinations they may receive and the inherent risks and benefits of these treatments/vaccinations. |
| | 9.2. | **Vaccination of Personnel** | | |
| **CWA 4.4.4.6.1** | 9.2.1. | Based on risk, the need for vaccination has been identified and covers groups identified as being potentially exposed to poliovirus. | | Measures should be implemented to identify non-responders to vaccination when needed (depending on the response rate of the vaccine) 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 where there are risks of exposure. Areas requiring vaccinations to enter should be posted.<br><br>Visitors, contractors and other non-core personnel should provide evidence of vaccination or evidence 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 examination of original certificates and crosschecking with medical practices responsible for administering the vaccine. |

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| | | | | The organization should ensure that the required or recommended vaccines are made available to the 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 Technique or use of PPE can be relaxed. |
| **CWA 4.4.4.6.1** | 9.2.2. | A vaccination policy has been defined and implemented. (If no, skip next question) | | |
| **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 shall ensure availability of inactivated polio vaccine (IPV) for individuals associated with the facility, consistent with the objectives to:<br>a. Restrict containment facility access 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:<br>– Personnel assigned to work within the containment perimeter;<br>– Contractors, auditors, and visitors who have a need to enter the containment perimeter;<br>– Support personnel and contractors working immediately outside the containment perimeter (e.g. maintenance personnel, cleaning staff).<br>b. Administer an IPV booster every three |

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| | | | | years to all personnel mentioned above or in the event of an antibody titre determined to be <1:8 on annual testing.<br>c. Provide effective secondary population safeguards by an established programme of education and promotion to encourage acceptance of immunization by:<br>– Non-core facility personnel, including contractors<br>– Worker's families/companions<br>– 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, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers. | | Procedures should ensure that there is adequate emergency planning provision to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, members of the broader community and to environmental conditions that may have been affected by the incident. This should include the identification of emergency scenarios, including infected worker / family member, together with the necessary support measures (e.g. liaison with emergency services / local authorities), provision of equipment and other resources required to |

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| | | | | manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines, etc.). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained.<br><br>Procedures should ensure that adequate first aid provision is available in relation to credible accident scenarios as identified during risk assessment. The procedures should address the need for adequate provision of trained personnel and their availability, as well as equipment and other materials that may be required in the provision of treatment.<br><br>Procedures should ensure that additional competent medical support is identified and made available (e.g. hospitals, isolation units, etc.). |
| | | **Element 10 – Emergency Response and Contingency Planning**<br><br>The Emergency Response and Contingency Planning element examines the structures and mechanisms in place to cope with working outside the normal operating conditions and how to react proportionately to emergency situations. Issues addressed include physical requirements; capacity in terms of personnel and facilities, protective and rescue systems; emergency communications; decision making authorities, and the development and testing of emergency scenarios and simulations.<br><br>**Sub-elements** | | |

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| | | 10.1. Emergency Scenarios<br>10.2. Emergency Response and Planning<br>10.3. Emergency Plans<br>10.4. Emergency Exercises and Simulations<br>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. | | In order that emergency planning can take place, it is necessary to consider all credible emergency scenarios. It is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, the rationale as to why issues were dismissed.<br><br>Scenarios considered should include:<br>a. infected / potentially infected worker or other contact (e.g. family member, emergency responder or community member);<br>b. accident or illness to worker within the containment area and need for evacuation;<br>c. fire;<br>d. flood;<br>e. breach of security;<br>f. explosion;<br>g. potential loss of poliovirus through theft |

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| | | | | or any other reason;<br>h. unexpected virulence (unknown biological agents or biological agents expected to be avirulent);<br>i. physical facility and equipment failure, including control system failure failure of disinfection regime;<br>j. utility failure including electricity, gas, steam and water supplies;<br>k. major spillage / aerosol release;<br>l. environmental release;<br>m. natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.);<br>n. act of terrorism or deliberate vandalism, extortion;<br>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:<br>1. Identify the potential for incidents and emergency situations involving biological agents, toxins and materials<br>2. Prevent their occurrence<br>3. Respond to emergency situations<br>4. Limit the likely 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.<br><br>A system shall be established to effectively manage a confirmed facility-associated poliovirus infection until the individual is free of poliovirus in stools for three consecutive | | g. |

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| | | days. This includes procedures for:<br>a. Isolating infected individuals, particularly from children and the unimmunized;<br>b. Securing collection and disinfecting stool and associated waste;<br>c. Educating families and frequent contacts on the risk posed by the poliovirus infection and procedures for isolation;<br>d. Communicating to relevant national and local officials to evaluate needs to implement community immunization response plans;<br>e. Notifying WHO;<br>f. Disinfecting areas potentially contaminated by infected individuals. | | |
| | 10.3. | **Emergency Plans** | | |
| | 10.3.1. | Biorisks are taken into account when preparing and implementing emergency plans.<br><br>A system shall be established to effectively manage incidents determined by the evaluation /response team as significant poliovirus exposures, including:<br>a. implementation of full preventive measures by isolating individuals under evaluation, particularly from children and the unimmunized, and securing stool and associated waste;<br>b. educating the individual under investigation, his/her family, and close contacts on the risk of poliovirus infection to the community, procedures for diagnosis, and precautionary measures necessary to prevent possible transmission;<br>c. initiating procedures to determine whether individuals are infected by collecting and testing nose, throat, and stool specimens daily for a minimum of 7 days post exposure.. | | The Organization should ensure that plans address as a minimum:<br>a. the identification of those responsible for devising, implementing and testing the control measures specified along with the communication and evaluation to all relevant personnel of competence in response;<br>b. the legality and enforceability of proposed emergency response plans<br>c. the need to respond during out-of-hours emergencies as well as those that occur during normal working hours;<br>d. provision for periods of reduced staff availability (e.g. during weekends and holiday periods);<br>e. the need for emergency access / exit, including the ability to override access controls as appropriate;<br>f. the need for emergency exit routes to |

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| | | | | g. avoid evacuating people through areas of higher biosafety or biosecurity;<br>g. the provision for safe removal, transport, transfer, treatment and accommodation of contaminated persons, objects;<br>h. the need to inform visitors and contractors of emergency response plans and the possible consequences of exposure.<br><br>d. |
| 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 intention that everyone is aware of their obligations. | | In the event of an emergency situation there may be a requirement to involve parties external to the organization. Based upon the credible scenarios identified, the organization should identify 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 as to their role and any risk exposures they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency (e.g. uncontrolled use of fire water). Contact information should be documented and made available to |

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| | | | | personnel responsible for coordinating the emergency response activity.<br><br>External agencies consulted may include:<br>a. police and security services;<br>b. fire services;<br>c. ambulance and local hospitals / healthcare providers;<br>d. transport providers / couriers;<br>e. local and national government officials;<br>f. environmental authorities;<br>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 in order to provide an assurance that plans are effective and to learn from any lessons that arise.<br><br>Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. 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 the exercise should be documented and reviewed for lessons learnt, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, |

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| | | | | allocated to named individuals and measures set 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. | | In the event of an emergency or unforeseen event there may be disruption to normal operating conditions. This could range from the need to safely shut down work in the event of a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively and contingency plans set 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 failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shut down of operations in extreme situations. |
| | | **Element 11 – Accident / Incident Investigation**<br><br>The Accident/ Incident Investigation element addresses activities directed toward defining the facts and circumstances related to the event, determining the causes, and developing remedial actions to control the biorisk and prevent future recurrence. Often, chance is the only reason a property damage accident or near-miss incident does not | | |

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| | | result in infection or personal harm. Likewise, chance alone often determines whether the consequences of the accident 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.<br><br>**Sub-elements**<br>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, analyze and learn from accidents and incidents involving poliovirus materials. | | Procedures should be set in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel, and may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed, and it is essential that lessons are learned and improvements are made where possible.<br><br>As a minimum, the accident / incident investigation process should include:<br>a. creating a culture of self-reporting of incidents, including “near misses” in addition to incidents that may trigger an investigation or emergency response;<br>b. identifying those responsible for maintaining the accident / incident |

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| | | | | reporting system;<br>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);<br>d. defining what constitutes a significant poliovirus exposure (e.g., ingestion) and thresholds for initiating procedures to determine whether individuals are infected;<br>e. specifying required documentation to support the system, frequency and distribution of reports generated, and communicated to relevant personnel;<br>f. identifying the reports that will be generated, their frequency and distribution;<br>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.<br>h. establishing and publicizing 24 hour accident / incident reporting channels, identifying those responsible for maintaining the system; |

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| | | | | i. ensuring analysis of trends;<br>j. identifying root causes using individuals trained in investigation techniques;<br>k. providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learnt result in action to avoid the repeat of such events and / or minimize their potential impact;<br>l. identifying where security professionals may be required to coordinate with law enforcement. |
| | | **Element 12 – Facility Physical Requirements**<br><br>The Facility Physical Requirements element looks at how the organization addresses biorisk during periods when something new is introduced or the existing setup is changed. Issues addressed include the people who need to be involved and consulted, how biorisk is incorporated into planning, the need to address commissioning in a structured way (including the role of suppliers), the physical characteristics of the materials used and any certification that may have to be carried out.<br><br>**Sub-elements**<br>12.1. Planning, Design and Verification<br>12.2. Commissioning and Decommissioning<br>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 upon 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 needs of the facility are determined through risk assessment. Engineering and operational solutions shall be incorporated that are consistent with the risk posed by the properties of materials that will 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 Biosafety Manual, 3rd ed.), industry good practices and facility-specific risk assessments. | | The design process should include the identification and review of relevant legislation and codes of practice (including building codes as well as those relating 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 the standards of acceptance to assure performance. The process should be documented and transparent to provide an assurance that it has been comprehensive and thorough. |
| CWA 4.4.4.8.1 | 12.1.3. | The design process identifies and consults all relevant parties associated with the facility and its operation. | | The design process should include the identification of and consultation with individuals involved in planning, construction, operation and maintenance of the facility. |

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| | | | | The following roles / individuals should be considered in terms of information requirements and need for consultation:<br>a. scientific personnel and other end users;<br>b. biorisk management advisor, biorisk management committee;<br>c. biosecurity and / or security personnel;<br>d. designers (architects and engineers);<br>e. constructors;<br>f. maintenance engineers;<br>g. materials and equipment suppliers;<br>h. commissioning agents;<br>i. certifiers;<br>j. regulators;<br>k. WHO<br>l. first responders;<br>m. other relevant parties identified in risk assessments.<br><br>If justified, based on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specification<br>1. is in line with accepted good practice;<br>2. incorporates features capable of providing assurance for control of poliovirus materials;<br>3. ensures relevant legislative requirements, and, standards, and risk assessment findings have been |

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| | | | | incorporated into 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 specification. | | |
| **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. | There is a formal process for:<br>1. Initial commissioning of new facilities<br>2. Final decommissioning of existing ones | | Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase at the first stage of science programme definition to assure that the expectations for the building are achievable. The commissioning plan should develop in detail in parallel with the physical concept to assure that the expectations for the building are measurable. The commissioning plan should clearly identify, with examples, all steps from beginning to end including conditions of acceptance of each step, as a pre-requisite of proceeding to the next.<br><br>The commissioning plan should identify all steps required before operation is commenced initially or resumed after temporary shutdown. The commissioning process should provide the benchmark for |

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| | | | | acceptable facility operation and the description of the programme to be put in place to maintain that level of performance.<br><br>The decommissioning process should identify the decontamination procedures and security-related measures that have to be in place for temporary or final shut down of the facility. The de-commissioning programme should not only describe the procedures to be undertaken, but also, the standards of acceptance when those procedures are performed.<br><br>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.<br><br>The poliovirus facility shall incorporate features that are guided by assessment of the risk of poliovirus reintroduction to the community and include the following provisions:<br>a. Poliovirus facilities are located in | Facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management.<br><br>The poliovirus facility shall incorporate features that are guided by assessment of the risk of poliovirus reintroduction to the community and include the following provisions:<br>a. Poliovirus facilities are located in | |

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| | | countries with demonstrated high national immunization coverage (= DPT3 coverage);<br>b. Poliovirus facilities are located in areas with closed sewage systems with secondary or greater treatment of effluents<br>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;<br>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.<br>e. The use of devices (e.g. BSCs) which 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 normal operation of the BSC (i.e. showering out not required when class III BSC is functioning properly). | countries with demonstrated high national immunization coverage (>90%);<br>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;<br>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;<br>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.<br>e. The use of devices (e.g. BSCs) which 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 normal operation of the BSC (i.e. showering out not required when class III BSC is functioning properly). | |

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| | | 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.<br>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).<br>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 mOPV2 for outbreak response is considered. Where evidence of 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.<br>i. Throughout the Poliovirus type 2 | 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.<br>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).<br>h. Controlled air system maintains directional airflow via a dedicated ventilation system with ductwork sealable for gaseous decontamination, HEPA filtration on exhaust, backflow protection on supply, and monitors/alarms to ensure directional airflow can be readily validated<br>i. Decontamination of all effluent | |

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| | | containment period, a dose of IPV will be introduced, high global vaccine coverage will be maintained, a dose of IPV will be introduced, population immunity is not expected to decline, and the use of mOPV2 for outbreak response is considered. Where evidence of satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, decontamination of effluents is not required. | (including shower water, eye wash, 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 measures to prevent release through traps, sinks and shower drains; | |
| | | j. Decontamination of all materials exiting the facility is achieved through a validated sterilization / decontamination procedure. Examples include:<br>– 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<br>– A material airlock / decontamination chamber sealable for gaseous decontamination;<br>– A dunk tank containing sufficient active compound to inactivate poliovirus.<br><br>The poliovirus animal facility shall | j. Decontamination of all materials including dead animals exiting the facility is achieved through a validated sterilization / decontamination procedure. Examples include:<br>– 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<br>– A material airlock / decontamination chamber sealable for gaseous decontamination;<br>– A dunk tank containing sufficient active compound to inactivate poliovirus.<br><br>The poliovirus animal facility shall | |

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| | | incorporate features guided by risk assessment as described above and shall meet all poliovirus containment criteria as described in this document including:<br>a. compliance with containment criteria for animal facilities that are consistent with the controls outlined in other sections of this document;<br>b. special training and supervision of personnel responsible for inoculating, harvesting, sampling, animal autopsies, and any other manipulations with poliovirus infected animals;<br>c. the use of devices (e.g. BSCs) which are validated to maintain primary containment is required for all animal manipulations with live poliovirus;<br>d. housing infected animals separately;<br>e. maintaining barriers to prevent escape of infected animals;<br>f. maintaining accurate records and accounting for all infected animals;<br>g. meeting international criteria for laboratory animal care;<br>h. security procedures specific for facilities housing animals involved in biomedical research | incorporate features guided by risk assessment as described above and shall meet all poliovirus containment criteria as described in this document including:<br>a. compliance with containment criteria for animal facilities that are consistent with the controls outlined in other sections of this document;<br>b. special training and supervision of personnel responsible for inoculating, harvesting, sampling, animal autopsies, and any other manipulations with poliovirus infected animals;<br>c. the use of devices (e.g. BSCs) which are validated to maintain primary containment is required for all animal manipulations with live poliovirus;<br>d. housing infected animals separately;<br>e. maintaining barriers to prevent escape of infected animals;<br>f. maintaining accurate records and accounting for all infected animals;<br>g. meeting international criteria for laboratory animal care;<br>h. security procedures specific for facilities housing animals involved in biomedical research | |
| | | **Element 13 – Equipment and Maintenance**<br><br>The Equipment and Maintenance element aims to make sure that all equipment which may have implications for control is selected with biorisk taken into consideration. | | |

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| | | Emphasis is placed upon selection procedures, maintenance of asset registers, control over where the equipment may be moved to and what it will be used for throughout its working life. Particular attention is also given to making sure the equipment functions properly by following prescribed periodic and predictive maintenance, supported by adequate breakdown response.<br><br>**Sub-elements**<br>13.1. Maintenance Management<br>13.2. Control of Equipment<br>13.3. Calibration<br>13.4. Certification<br>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 impact on biorisk is 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.<br><br>In planning and conducting maintenance activities the organization should consider:<br>a. adequately maintaining the physical integrity of the facility and its fixtures and fittings; |

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| | | | | b. ensuring maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment;<br>c. ensuring adequate controls are in place to prevent workers being exposed to poliovirus in the course of their work<br>d. identifying and recording maintenance requirements at time of construction of facilities, or purchase / acquisition of equipment;<br>e. creating and maintaining a maintenance register for all applicable equipment;<br>f. identifying and conducting planned maintenance activities at an appropriate frequency;<br>g. ensuring adequate provision for unplanned (breakdown) maintenance to ensure integrity of the facility is maintained at all times;<br>h. determining and monitoring predictive maintenance requirements and associated indicators and monitors;<br>i. ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement;<br>j. a pest control programme.. |

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| | 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 impact on biorisk is 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:<br>a. identifying equipment in line with identified work needs, which can be demonstrated as fit for purpose;<br>b. controlling purchase / acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel;<br>c. controlling entry and exit of equipment to and from the poliovirus facility, including decontamination requirements (e.g. air locks and decontamination)<br>d. ensuring the asset register is regularly updated<br>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 impact on biorisk is 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:<br>a. identifying and recording calibration requirements at time of purchase / acquisition;<br>b. identifying the standards / tests that will be used to ensure the equipment is correctly calibrated; |

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| | | | | c. establishing procedures to conduct calibrations on equipment used in live virus areas<br>d. creating a documented and up-to-date calibration register for all applicable equipment;<br>e. ensuring calibration is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment. |
| | 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 impact on biorisk is 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:<br>a. identifying and recording certification requirements at time of purchase / acquisition of equipment, including relevant and current standards against which to certify;<br>b. ensuring competent and independent certifiers are used for the certification process;<br>c. ensuring certification is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment. |
| | 13.5. | **Validation** | | |

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| **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 impact on biorisk is 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:<br>a. identifying and recording validation requirements at time of purchase/acquisition;<br>b. identifying the standards/tests that will be used to ensure the equipment is correctly validated;<br>c. creating a documented and up-to-date validation register for all applicable equipment;<br>d. ensuring validation is scheduled and conducted in the line with manufacturer's requirements and / or other specified intervals as identified by risk assessment;<br>e. ensuring competent and independent validation parties are used for the validation process.<br><br>For physical security systems, the analogous concept is performance testing; evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed. |
| | | **Element 14 – Decontamination, Disinfection and Sterilization**<br><br>The Decontamination, Disinfection and Sterilization element examines the controls in place to ensure that appropriate disinfection, decontamination and sterilization routines are in place to manage the risk presented by the organisms and work activities | | |

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| | | undertaken. The element addresses general requirements for procedures, training and waste disposal but also looks at more specific issues including the potential need for specialist laundering and issues specific to animal facilities.<br><br>**Sub-elements**<br>14.1. Management of Biological Waste<br>14.2. Inactivation of Biological Agents and Toxins | | |
| | 14. | **DECONTAMINATION, DISINFECTION AND STERILISATION** | | |
| | 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.<br><br>No viable poliovirus shall 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 shall be identified and adequate prevention measures set 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:<br>a. ensure programme is in place to minimize the waste production;<br>b. ensure effective waste audit trails are in place and documented;<br>c. provide adequate facilities and procedures for the storage of waste (including short term storage);<br>d. ensure methods are available for effective segregation and decontamination of mixed waste (e.g., infected animals that have received radioactive materials);<br>e. ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and |

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| | | | | 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:<br>1. Identified<br>2. Documented | | Sources of contamination that should be considered include:<br>a. personnel;<br>b. clothing and PPE;<br>c. glassware;<br>d. equipment;<br>e. cultures and associated materials;<br>f. spill clean-up materials and equipment;<br>g. possibly infectious microorganisms and toxins and contaminated materials;<br>h. paper and plastic waste;<br>i. needles, syringes and sharps;<br>j. waste water, including that from sinks and showers;<br>k. air;<br>l. filters and air handling systems;<br>m. discarded equipment used in the facility;<br>n. animals exposed to laboratory poliovirus;<br>o. animal carcasses and bedding;<br>p. facilities.<br><br>All potential waste streams and other sources of contamination should be identified and documented.<br><br>For each of these sources, procedures should be put in place to validate the decontamination regime and records shall |

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| | | | | demonstrate that no contaminated persons / materials leave the facility and inactivation measures have been implemented effectively. |
| **CWA 4.4.4.5.2** | 14.1.3. | Effective 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 it may be necessary to hold contaminated dedicated equipment such as fire fighter apparel or ambulance tools on site if they cannot be effectively decontaminated.<br><br>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 that appropriate methods for disinfection and decontamination are chosen and implemented effectively.<br><br>Procedures shall be established, validated, and maintained for effective poliovirus decontamination of the facility.<br><br>Inactivation of Poliovirus. Procedures shall be established and maintained to ensure | | Whatever the poliovirus materials handled, it is likely that a number of effective inactivation methods will be available. The organization should ensure that there are data available to demonstrate that the methodology selected is capable of inactivating the poliovirus materials under |

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| | | complete inactivation of all poliovirus from all materials and solid waste streams leaving the containment perimeter such that<br>a. Heat sterilization (autoclaving) shall be the preferred method of inactivation of poliovirus;<br>b. SOPs are available to address both routine and non-routine activities (e.g. daily routines vs. major spills);<br>c. SOPs are developed to respond to failure of decontamination procedure or equipment<br>d. SOPs are validated and shown to be effective against poliovirus prior to their use;<br>e. All materials leaving the containment perimeter (including clothing liquid / solid waste) are heat sterilized or subject to chemical treatment of proven effectiveness prior to removal;<br>f. All material leaving the containment perimeter is accompanied by documentation of its decontamination<br>g. Resources are available to deal with emergencies, accidents, and other incidents;<br>h. In the event that live poliovirus is to be removed from the facility this will be done through use of a dunk tank, decontamination chamber or other validated mechanism that ensures disinfection of the exterior surfaces of any packaging materials used;<br>i. The facility inactivates all waste and other potentially contaminated material before it is passed to contractors or other third parties for waste disposal. | | the specific conditions encountered in the facility. Validation measures should consider issues including;<br>a. the nature of the material being treated (e.g. volume, presence of protein / other potentially inhibitory substances;<br>b. contact times, materials compatibility issues (e.g. interaction with stainless steel or rubber seals):<br>c. potential health hazards associated with the disinfectant;<br>d. the need to maintain the required level of active compound, including deterioration over time.<br><br>In planning and conducting decontamination activities the organization should consider:<br>i ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and that such concentrations are maintained throughout the process, including conducting specific validation activities where necessary;<br>ii providing adequate facilities and procedures for the storage of waste (including short term storage);<br>iii ensuring methods are available for effective decontamination of mixed waste (e.g., infected animals that have |

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| | | | | received radioactive materials);<br>iv ensuring that where appropriate, methods are available for decontamination of sensitive equipment or that which is not suitable for autoclaving (e.g. computers);<br>v implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and use of indicators in autoclaves);<br>vi decontaminating protective clothing by appropriate means prior to leaving the facility;<br>vii ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside the facility;<br>viii implementing programmes to ensure the amount of contaminated waste is minimized. |
| | | **Element 15 – Transport Procedures**<br><br>The Transport Procedures element explores how an organization deals with issues associated with internal and external transport of biological materials, and looks at the necessary roles and responsibilities, materials and equipment, including the need to work with specialist couriers and shipping agents.<br><br>**Sub-elements**<br>15.1. Transport procedures | | |

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| | | | | |
| | 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:<br>a. ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines;<br>b. ensuring internal transport of poliovirus (within the facility, but outside the containment perimeter) meets equivalent biosafety and biosecurity standards required for external transport outside the facility;<br>c. ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transportation process;<br>d. selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely;<br>e. whether a request for poliovirus materials is being made by an approved facility for a legitimate reason, and equivalent controls are applied to importation of material to the facility;<br>f. the need is identified for formal |

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| | | | | documented transfer forms signed by the responsible management representative authorizing movement of materials.<br>g. document control that allows traceability of material movements;<br>h. identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation of poliovirus materials, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off. |
| | | **Element 16 – Security**<br><br>The Security element examines how an organization manages security with regard to biorisk. The element looks at some of the more obvious issues like access control, but also the need for information security and support from external agencies.<br><br>**Sub-elements**<br>16.1. Physical Security<br>16.2. Information Security<br>16.3. Personnel Control<br>16.4. Personal Security<br>16.5. Contractors, Visitors and Suppliers | | |
| | 16. | **SECURITY** | | |
| | 16.1. | **Physical Security** | | |

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| **CWA 4.4.4.8.4** | 16.1.1. | Controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained. | | Measures should be set 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.<br><br>In planning and conducting security risk assessments the organization should consider:<br>a. theft or diversion of poliovirus materials or related equipment, documents or data;<br>b. sabotage including vandalism and tampering;<br>c. break-in and intrusion;<br>d. labour issues and disputes;<br>e. kidnapping and extortion;<br>f. weather-related emergencies (i.e., earthquake, tsunami, flood, tornado, and hurricane);<br>g. workplace violence;<br>h. utilities failure;<br>i. picketing, occupation and barricade;<br>j. screening and isolation of suspect packages;<br>k. acts of terrorism;<br>l. civil unrest or war;<br>m. cyber threats . |

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| | | | | Care should be taken to coordinate biosecurity measures with those of biosafety to manage and minimize conflicting priorities.<br><br>Breaches of security should be reported, recorded and investigated as accidents and incidents.<br><br>Procedures for the physical security of poliovirus materials including cultures, specimens, samples and potentially contaminated materials should be implemented and maintained such that:<br>a. The containment facility shall be located on a secure site with perimeter control to discourage unauthorized access;<br>b. The containment facility shall be located away from uncontrolled traffic flows and entrance shall be via a locked door with two-factor access control measures (e.g. requirement for electronic pass with personal access code);<br>c. During poliovirus manipulations, a second person within the containment perimeter or in close proximity should be aware of the work being conducted and available for contact if needed;<br>d. The perimeter of the facility shall be subject to constant monitoring, e.g. the |

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| | | | | use of alarms, security personnel and closed circuit TV;<br>e. Measures shall be implemented to identify and record all personnel in the facility at any point in time<br>f. Anti-intrusion alarms and sensors shall be installed including interfaces with police and other security services;<br>g. Panic buttons and 'silent' emergency alert measures shall be 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 is 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 unauthorized release of such information are critical.<br><br>Procedures addressing information security should consider:<br>a. 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; |

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| | | | | b. computer security including robust internet firewalls and encryption protocols;<br>c. strict policies regarding PC's, laptop computers, storage media, cameras, etc. entering or leaving the facility;<br>d. thorough destruction of paper files to be discarded and complete erasure of unwanted electronic files;<br>e. security measures and procedures |
| 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 personnel reliability assessment measures required should be determined as part of the risk assessment process. The organization shall ensure that access to poliovirus containment areas is limited to personnel that have been screened for subversive behaviors / associations or criminal records or are accompanied at all times by authorized individuals (as in the case of visitors, contractors, etc.). The screening includes:<br>• Association with organizations that could present a threat to integrity of the facility;<br>• Medical conditions that could lead to unstable / undesirable behavior; |

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| | | | | • Providing assurance that individuals do not work under the influence of drugs or alcohol. |
| **CWA 4.4.4.7.1** | 16.3.2. | The organization shall ensure that access to facilities or work is controlled for individuals according to the policy. | | Where lawful and appropriate as determined by risk assessment, screening may include such checks as identity and immigration status, membership of 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 that include, where appropriate, personal security awareness training.<br><br>Documented security drills and exercises shall be 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 sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility. | | |

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



## *Introduction*

A facility-associated poliovirus infection or release into the environment during the Endgame 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 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; design and operation of the containment facility; practices and procedures; 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 an essential containment facility and consist of a national routine childhood immunization policy and demonstrated high (=DPT3; >90%) national population coverage (World Health Organization, 2006). Tertiary safeguards of facility location minimize the risk of transmissible poliovirus by placement of such facilities in areas with closed sewage systems with secondary or greater effluent treatment. . Primary

and secondary safeguards are required within 3 months of the tOPV-bOPV switch for essential facilities handling and storing only OPV2/Sabin2 materials, and 3 months after bOPV cessation for essential facilities handling and storing any OPV/Sabin materials.

This *Biorisk management standard for essential poliovirus facilities holding only OPV/Sabin poliovirus materials* describes the international requirements for primary safeguards established for essential poliovirus laboratory handling and storing OPV/Sabin materials or Sabin-IPV production facilities (Annex 3). The *Standard* is based on *CWA15793, Laboratory Biorisk Management* (CEN, 2011), the principles of the WHO *Laboratory Biosafety Manual* (3rd Edition, 2004) and the extensive poliovirus scientific literature spanning nearly 7 decades (Dowdle WR et al., 2006)). The *Standard* serves as the framework for national and international certification (Annex 4: *International certification of poliovirus facilities* in the Endgame period and in the post-eradication/post-OPV era*)*. It consists of 16 elements and sub elements 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. The *Standard* further assumes that essential facility personnel and management at all levels fully appreciate the enormity of the consequences of accidental or deliberate 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 (REF?). Infectivity is inactivated by dehydration, heat (>50 °C), or treatment with dilute solutions of formaldehyde or bleach at appropriate concentrations.

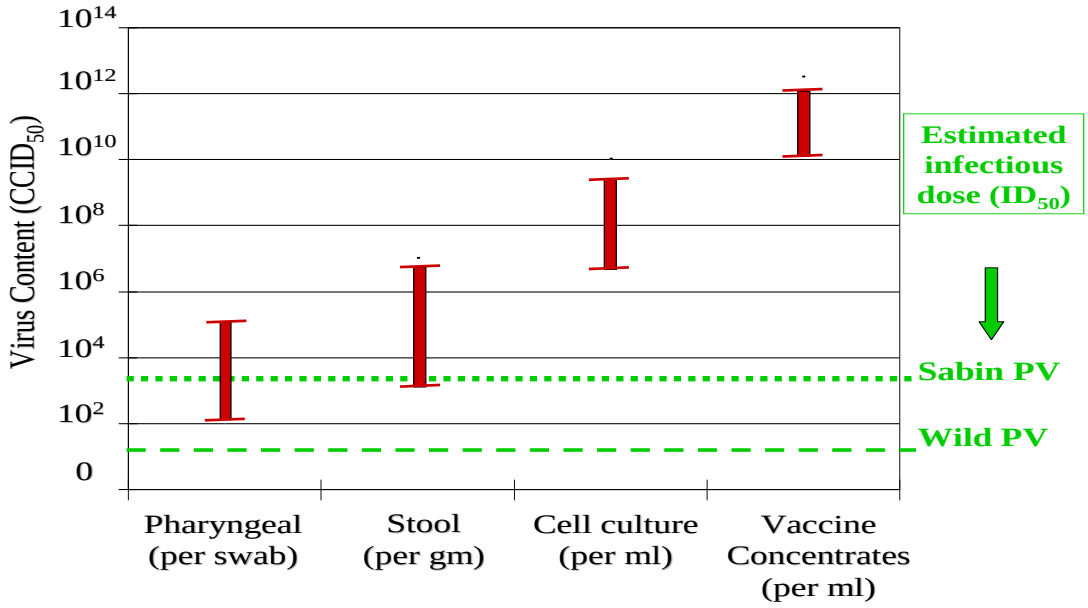
The most common routes of exposure to infectious agents in the facility environment are: 1) ingestion, 2) inhalation, 3) injection, and 4) contaminated skin and mucous membranes. The infectious dose is a factor of virus virulence, route of presentation, and virus particles in sufficient number to overcome mechanical loss and natural and immune host defenses. In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/gm (Sabin) to $10^{4.3}$ $CCID_{50}$/gm (wild) in stool samples, to$10^{8}$ $CCID_{50}$/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 3 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 or re-infection of the gut (REF?). Ingestion of poliovirus may result from any laboratory operation, activity, or incident that leads to 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

$\pm 10^3$ $CCID_{50}$ 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 ingestion of sufficient poliovirus particles. Droplets created by sprays, spills, and splash of poliovirus cell cultures ($10^8$ $CCID_{50}$) and concentrates ($10^{11}$ $CCID_{50}$) constitute the highest personnel exposure risks (Figure 2).

Inhalation, defined as exposure to small particle aerosols <5 µm (droplet nuclei) deposited predominately in the lower respiratory tract, has been identified as a possible route of infection for poliovirus (REF?). 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 infection through mucociliary transport to the pharyngeal region. Inhalation risks may be further reduced in facility environments maintained at low relative humidity (<50%) (REF?). Antibodies acquired through immunization greatly reduce infection risks through injection or breaks in skin or mucous membranes.

Figure 2: 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) release of contaminated air, 3) contaminated effluents and waste water recovered form secondary sewage treatment plants, 4) uncontrolled transport of infectious material, 5) solid waste transported to landfills, 6) contaminated equipment or materials removed from the facility, 7) escape of infected animals, and 8) a deliberate theft or release of infectious agents from a facility. Exposure risks through the latter four routes (4-7) are low for poliovirus facilities that adhere to international regulations for the transport of infectious substances, Good Laboratory Practice, and

[19] Estimated ingestion 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 ingestion of sufficient poliovirus particles.

Good Manufacturing Practice and likely low for inhalation of contaminated air effluent where facilities maintain low relative humidity environments and exhaust air away from direct human exposure. Exposure risks through ingestion of effluents range between high and low, depending on poliovirus content of facility effluent, sewerage system size and integrity, and potential for human consumption. Risks of community exposure are highest through facility personnel unknowingly contaminated or infected with poliovirus. Routine IPV immunization of facility personnel may greatly reduce the risk of intra- and extra-household transmission.

Effective poliovirus risk management is achieved by careful assessment of exposure risks, 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 infection of laboratory workers by ingestion. Airborne transmission is conceivable but not demonstrated and infection through parenteral exposure such as needle stick is unlikely in immunized individuals.

***Management system elements***

| ***Biorisk management standard for essential poliovirus facilities holding only OPV/Sabin poliovirus materials*** | | | |
|---|---|---|---|
| ***CWA 15793 Clause No[20]*** | ***Biorisk Management Element No*** | ***Requirements for <u>Containment of WPV2</u>*** | ***Guidance*** |
| | | **Element 1 – Biorisk Management System**<br><br>The Biorisk Management System element examines the system and policy in place to manage the laboratory biorisk. Effective management and organization are vital to the success of any activity, and management commitment and leadership lays 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 towards managing risk will be ineffective. The way management thinks and acts, has a major impact on performance.<br><br>**Sub-elements**<br>1.19. Biorisk Management Policy<br>1.20. Objectives, Targets and Programme<br>1.21. Roles, Responsibilities and Authorities<br>1.22. Records, Document and Data Control<br>1.23. Analysis of Data<br>1.24. Change Management<br>1.25. Consultation and Communication<br>1.26. Programme of Work<br>1.27. Work Planning and Capacity<br>1.28. Legal Requirements<br>1.29. Continual Improvement<br>1.30. Preventive Action<br>1.31. Control of Non-Conformities | |

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

| ***Biorisk management standard for essential poliovirus facilities holding only OPV/Sabin poliovirus materials*** | | | |
|---|---|---|---|
| ***CWA 15793 Clause No[20]*** | ***Biorisk Management Element No*** | ***Requirements for <u>Containment of WPV2</u>*** | ***Guidance*** |
| | | 1.32. Inspection and Audit<br>1.33. Corrective Action<br>1.34. Contractors and Suppliers<br>1.35. Biorisk Management Review<br>1.36. Biorisk Management System | |
| | 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:<br>4. Development<br>5. Authorization<br>6. 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:<br>3. The overall biorisk management objectives<br>4. A commitment to improving biorisk management performance | The policy should require all projects/work areas to be assessed for risks and a full assessment prepared before work is approved to commence. |
| **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:<br>8. Protecting staff, contractors, visitors, community and environment from poliovirus | Including the need to conduct risk assessments and implement the required |

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| | | materials that are stored or handled within the facility<br>9. Reducing the risk of unintentional release of, or exposure to poliovirus materials<br>10. Reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials<br>11. Complying with all legal requirements applicable to the poliovirus materials that will be handled or possessed, and with the requirements of this standard<br>12. Ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements<br>13. Effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups<br>14. Continually improving biorisk management performance | control measures. |
| | 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:<br>4. Established<br>5. Implemented<br>6. 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 investigation of incidents and accidents and improving controls and their implementation and by ensuring that adequate resources are provided to maintain the effectiveness of the controls.<br><br>Note: Refer to Element 2 – Risk Assessment. |

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| | 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 management of biorisk rests with top management but tasks may be delegated through the organization provided that 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 the standard. It is important to define roles and responsibilities and that there is clear communication within the Organization in terms of the actions that need to be taken, and who has the required authority. |
| **CWA 4.4.1.1** | 1.3.2. | Top management ensures that roles, responsibilities and authorities 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.<br><br>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 the titles used in specific organizations. |

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| **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 operational responsibility for overseeing the system for management of biorisk. | 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. | Functions of the senior manager for the management of biorisk include:<br>5. Providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility<br>6. Reporting to top management on the performance of the biorisk management system and any need for improvement<br>7. Ensuring promotion of the biorisk management system throughout the organization<br>8. 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 biorisk management needs of the facility (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 and may be either a dedicated function, or the role can be addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management advisor(s), security manager and the occupational health professional. Dependent on the nature of |

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| | | | the agenda or nature of the work others may be included e.g. the facility manager and /or worker and community representatives. |
| **CWA 4.4.1.3** | 1.3.7. | The biorisk management committee reports to senior management, and:<br>6. Has documented terms of reference<br>7. Includes a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken<br>8. Ensures issues addressed are formally recorded, actions allocated, tracked and closed out effectively<br>9. Is chaired by a senior individual<br>10. Meets at a defined and appropriate frequency, and when otherwise required | Functions of the committee should include:<br>e. contributing to the development of institutional biorisk policies and codes of practice;<br>f. approving proposals for new work or significant modifications to the potential risk associated with existing activities;<br>g. reviewing and approving protocols and risk assessments for work involving polioviruses;<br>h. reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs.<br><br>The list of roles for the biorisk management committee is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed. |
| **CWA 4.4.1.4** | 1.3.8. | A competent individual(s) is 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 (BSO) or biological safety advisor. This function should normally be regarded as an advisory position and not directly |

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| | | | responsible for managing biorisk, as this rests with those conducting and managing the work within the organization (e.g. scientific director, principal investigator, department head, laboratory manager, group leader, etc.). The role and knowledge of the biorisk advisor is important to develop, implement, maintain and continually improve a biosafety and biosecurity programme based on a management system. The advisor should be competent to perform the role, and allocated sufficient time and other resources to do the job effectively. |
| **CWA 4.4.1.4** | 1.3.9. | The Biorisk management advisor role is independent of those responsible for implementing the programme of work. | In the execution of his/her biorisk management duties the advisor 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 advisor:<br>3. Reports directly to the responsible senior manager<br>4. Has delegated authority to stop work in the event that it is considered necessary to do so | Functions of the biorisk management advisor should include:<br>g. verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed;<br>h. advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to |

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| | | | management / biorisk management committee;<br>i. ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other personnel as necessary;<br>j. advising on biorisk management issues within the Organization (e.g. management, biorisk management committee, occupational health department, security);<br>k. contributing to the development and / or delivery of biorisk training activities;<br>l. ensuring that all relevant activities are performed in compliance with biorisk regulations and that required biorisk authorizations for work are in place.<br><br>The list of roles for the biorisk management advisor is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed. |
| **CWA 4.4.1.5** | 1.3.11. | An individual(s) with responsibility for the scientific programme within the facility has been designated with responsibilities relevant to biorisk management. | The scientific manager is the individual 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. adherence to policies and procedures, monitoring staff performance and participation in |

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| | | | inspections and audits). The individual would normally have an in-depth knowledge of the work programme and the facility and be in a supervisory / management position and may be referred to as Head of Department, Principal Investigator, Laboratory Supervisor / Manager or Group Leader. Competence will be required in technical / scientific aspects of the poliovirus materials being used and their control, together with 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 so as to avoid any omissions and ensure consistency. |
| **CWA 4.4.1.5** | 1.3.12. | The scientific management functions include:<br>7. Ensuring that all work is conducted in accordance with established policies and guidelines described in this standard<br>8. Supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility<br>9. Planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available<br>10. Ensuring required authorizations for work are in place<br>11. Ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place<br>12. Ensuring that 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) | |

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| **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 understanding of the poliovirus materials that are handled within the facility.<br><br>The role should include providing input into risk assessment from a worker health perspective, advising on first aid / emergency treatment measures and follow-up, liaising with external healthcare providers, and coordinating medical examinations, surveillance and vaccination programmes.<br><br>Roles and responsibilities of the occupational health professional 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 activities and risks of the facility. | |
| **CWA 4.4.1.7** | 1.3.15. | A facilities manager(s) has been appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this Polio Biorisk Management Standard. | The facilities manager would normally be an engineer or someone 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 |

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| | | | work, and liaising with contractors. Roles and responsibilities of the facilities 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 so as to avoid any omissions and ensure consistency. |
| **CWA 4.4.1.8** | 1.3.16. | A security manager has been designated with responsibilities determined in accordance with requirements set out in this Polio Biorisk Management Standard. | The security manager would normally be someone with an in-depth knowledge of laboratory and facility security, who should liaise with other personnel (e.g., biorisk management advisor) 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. Roles and responsibilities of the security personnel 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 maintained, an animal care manager has been designated with responsibilities determined in accordance with requirements set out in this Polio Biorisk Management Standard. | The animal care manager would normally be someone with 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 advisor, occupational health professional, etc.) to implement effective and proportionate laboratory biosafety and |

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| | | | laboratory 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 and use perspective. |
| | 1.4. | **Records, Document 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 upon 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.<br><br>Documented records shall be maintained in paper or electronic form for a minimum period of 10 years from the day of withdrawal and be available in English for review during national/international certification procedures. | Controlled documents may include:<br>h. risk assessments, standard operating procedures (SOPs) and safety manuals;<br>i. job hazard analyses and charts of authority;<br>j. design records and commissioning / test plans, maintenance plans and records and all associated data;<br>k. audit and inspection checklists;<br>l. laboratory biosecurity manuals and risk assessments, authorizations and other security documents;<br>m. training records;<br>n. containment equipment certifications.<br><br>The list of controlled documents is neither exhaustive nor comprehensive but includes |

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| | | | 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 time and disposal of records. A procedure should be established to define the controls needed to approve documents prior to issue or public release to ensure sensitive information such as specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls for review, update and re-approval of documents, and for the change control and revision process. |
| | 1.5. | **Analysis of Data** | |
| **CWA 4.5.1** | 1.5.1. | Appropriate data are determined, collected and analyzed 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 the scope of operations. The results of the analysis should be applied in the management review. |

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| | 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. | The changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include evaluation of the effect of the changes on the risk assessment.<br><br>The following are examples of changes that should be subject to the change management process:<br>i. modifications to buildings and equipment or their operation, which may or would have an effect on biorisk;<br>j. introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel);<br>k. changes to the programme of work, including alterations to work flow or volume which may or would have an effect on biorisk;<br>l. alterations to SOPs, including significant changes in materials or reagents;<br>m. modifications to entry / exit protocols;<br>n. modifications to personnel policies and visitor protocols;<br>o. modifications to disinfection, decontamination and other waste management methodologies; |

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| | | | p. changes associated with PPE provision and usage. |
| | 1.7. | **Consultation and Communication** | |
| **CWA 4.4.4.3** | 1.7.1. | Relevant biorisk information relating to the organizations activities is communicated to and from employees and other relevant parties. | The organization should implement mechanisms to ensure that relevant and current information with the potential to affect workers and others is defined and delivered effectively at appropriate intervals. In the workplace this could mean regular team meetings and briefings, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others including:<br>g. local, national and international governmental Organizations;<br>h. relevant regulatory agencies;<br>i. certifiers;<br>j. emergency services and healthcare providers;<br>k. contractors and suppliers (e.g. cleaners, maintenance providers, security personnel);<br>l. local community representatives (e.g. through a community liaison committee).<br><br>Systems should be set in place to identify existing or emerging technologies or other relevant information relating to the containment of the poliovirus materials |

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| | | | being handled or stored, and that this information is shared with relevant staff through the use of appropriate media. This may include circulation of appropriate signage, documents, team briefings and 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 pertaining to the biorisks of the organization. | |
| | 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 of work 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, etc). All activities associated with the work programme should be specified and supported by formal SOPs approved in accordance 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. | |

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| | 1.9. | **Work Planning and Capacity** | |
| **CWA 4.4.4.3** | 1.9.1. | There is sufficient resource capacity and capability 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 regulatory requirements with which the organization shall comply. | The organization should adopt measures to identify legal and other requirements for the facility in relation to the poliovirus materials that will be held and used, but also other regulations including for example: worker protection and rights, environmental impact and general health & safety (e.g. fire, electrical, etc.). There is a need to monitor for new and upcoming requirements, as well as those already in existence. This information should be kept up to date and the requirements incorporated into the biorisk management system of the facility. |
| | 1.11. | **Continual Improvement** | |
| **CWA 4.1.2** | 1.11.1. | The organization continually improves the effectiveness of the biorisk management system through the use of:<br>• the policy,<br>• objectives,<br>• self-audit programme,<br>• audit results, | The organization should strive to continue to develop and refine the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved through objective setting and targets placed upon those |

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| | | • analysis of data,<br>• risk assessment,<br>• corrective and preventive actions and<br>• the management review. | working within the facility, and 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 in order to prevent their occurrence. | A procedure should be established to define requirements for:<br>g. determining the potential non-conformities and their causes;<br>h. evaluating the need for action to prevent<br>i. occurrence of non-conformities;<br>j. determining and implementing action needed;<br>k. recording of the results of action taken;<br>l. reviewing 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 Non-Conformities** | |
| **CWA 4.5.4.2** | 1.13.1. | Situations that do not conform to the requirements of the Laboratory Biorisk Management Standard are identified and controlled to prevent undesirable consequences. | The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure. |
| **CWA 4.5.4.2** | 1.13.2. | Records of the nature of the non-conformity and any subsequent action taken are maintained. | |

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| | 1.14. | **Inspection and Audit** | |
| **CWA 4.5.5** | 1.14.1. | A programme of inspection and audit is conducted which is appropriate to the risk associated with the facility. | Inspections may be frequent checks on specific areas conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels / concentrations and air exchange rates / maintenance of directional air flow), or 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, not just in time for scheduled inspections. Audits should be performed by competent individuals who are independent of the activity being audited. Records should be maintained of findings of inspections / audits, including action taken to close out any non-conformities or 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 to the requirements of this Polio Biorisk Management Standard, and that it is effectively implemented and maintained.<br><br>*National inspection and audit.* A program of unannounced inspection and audit shall be conducted, no less than annually, by national authorities to determine if the biorisk management system conforms to the requirements of this standard and is functioning properly and that necessary corrective actions are taken and verified without undue delay. | |

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| | | *International inspection and audit*. Top management shall ensure that information and access necessary for the periodic comprehensive international review of the poliovirus facility is made available in English as requested by the international review team (REF WHA 2015?) 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 routine OPV 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 non-conformities and their causes. | |
| **CWA 4.5.5** | 1.14.4. | Follow-up activities arising include:<br>3. The verification of the actions taken<br>4. Reporting of verification results | |
| | 1.15. | **Corrective Action** | |
| **CWA 4.5.4.3** | 1.15.1. | Action is taken to eliminate the causes of non-conformities with the requirements of this *Biorisk management standard for essential poliovirus facilities holding WPV materials (BRM WPV)* in order to prevent recurrence. | A procedure should be established to define requirements for:<br>g. reviewing the non-conformities;<br>h. determining the cause of non-conformities;<br>i. evaluating the need for action to ensure that non-conformities do not recur;<br>j. determining and implementing action needed;<br>k. recording results of action taken;<br>l. reviewing corrective actions taken. |
| **CWA 4.5.4.3** | 1.15.2. | Corrective actions are appropriate to the effects of the nonconformities encountered. | |

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| | 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 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 impact on biorisk, there are many that may. Suppliers that should be considered include, but are not limited to, those that provide:<br>g. cleaning services;<br>h. laboratory equipment;<br>i. waste management or disposal services;<br>j. IT support services;<br>k. equipment and facility maintenance services;<br>l. 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 of the results of evaluations and any necessary actions arising from the evaluation are maintained. | |
| | 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 at a defined frequency determined by the needs of the |

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| | | | organization, but at least annually. |
| **CWA 4.6.1** | 1.17.2. | The review includes:<br>2. Assessing opportunities for improvement<br>The need for changes to the system, procedures, policies and objectives | The review input should include information on:<br>i. results of audits;<br>j. compliance to SOPs and work instructions;<br>k. status of risk assessment activities;<br>l. status of preventive and corrective actions;<br>m. follow-up actions from previous management reviews;<br>n. changes that could affect the system;<br>o. recommendations for improvement;<br>p. results of accident / incident investigations. |
| **CWA 4.6.1** | 1.17.3. | Records from the management review are maintained. | The review output should include decisions and actions related to:<br>iv improvement of the effectiveness of the biorisk management system;<br>v improvement related to the requirements and risk assessments;<br>vi 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 in accordance with the requirements of this Polio Biorisk Management Standard. | |

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| | | **Element 2 - Risk Assessment**<br><br>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.<br><br>**Sub-elements**<br>2.1. Process, Methodologies and Procedures<br>2.2. Assessment Timing and Scope<br>2.3. Roles and Responsibilities<br>2.4. Hazard Identification<br>2.5. Risk Assessment<br>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 in accordance with this Polio Biorisk Management Standard. | |
| **CWA 4.3.1.1** | 2.1.2. | The performance of the risk management system 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 that are 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. | |

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| | 2.2. | **Assessment Timing and Scope** | |
| **CWA 4.3.1.2** | 2.2.1. | The approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive. | The following should trigger either a new risk assessment or review of an existing one:<br>i. commencement of new work or changes to the programme of work including the introduction of new biological agents or alterations to work flow or volume;<br>j. new construction / modifications to laboratories, plant and equipment or its operation;<br>k. introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel);<br>l. significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, PPE provision / usage entry / exit protocols, etc.);<br>m. when unexpected events that may have relevance for the management of biorisks are observed;<br>n. when actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major |

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| | | | accident exposure);<br>o. when considering emergency response and contingency planning requirements;<br>p. as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).<br><br>There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required. One framework which organizations may consider adopting is outlined in Figure 1 of CWA 15793:2011 (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 the assignment of trained personnel for management, performance of work, 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 do one of the following:<br>f. initiate action to prevent or reduce the adverse effects of risk;<br>g. control further treatment of risks until the level of risk becomes acceptable;<br>h. identify and record any problems |

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| | | | relating to the management of risks;<br>i. initiate, recommend or provide solutions through designated channels;<br>j. 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:<br>3. Identified<br>4. Documented | The first stage in the risk management process is to identify all hazards that are relevant for 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.<br><br>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 will include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.<br><br>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.<br><br>A hazard identification exercise should use information including:<br>k. group experience and knowledge;<br>l. external or specialized expertise not found in the facility;<br>m. results of previous assessments;<br>n. surveys of previous accidents/incidents;<br>o. hazardous materials data;<br>p. information on hazardous organisms;<br>q. guidelines and codes of practice;<br>r. facility drawings;<br>s. SOPs, manuals, etc.;<br>t. process maps.<br><br>Defined methodologies and approaches are available for conducting hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and associated activities. Hazard identification should be appropriate in nature, structure and recorded to a level whereby others can review the process. |
| | 2.5. | **Risk Assessment** | |

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| **CWA 4.3.1.4** | 2.5.1. | Suitable methodologies for assessing and recording risks are:<br>4. Identified<br>5. Implemented<br>6. Maintained | The risk assessment should categorize risks to identify those which 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 through the use of a risk matrix identifying likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate.<br><br>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 made of the inherent risk from polioviruses(e.g. from risk grouping descriptions, material safety data sheets etc.). After definition and implementation of control measures the risks should be reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented. |
| | 2.6. | **Risk Control** | |
| **CWA 4.3.1.5.** | 2.6.1. | Suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval | The risk management approach should include a control plan to include: |

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| | | mechanisms are:<br>4. Identified<br>5. Implemented<br>6. Maintained | e. who is responsible and accountable for implementation of the plan;<br>f. what resources are to be utilized (e.g. people, budget);<br>g. timetable for implementation;<br>h. details of the mechanism and frequency of review of compliance with the plan.<br><br>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 personal protective equipment (PPE). |
| | | **Element 3 – Poliovirus Inventory and Information**<br><br>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 will depend upon the pathogens being held, and will range in complexity from simple lists to secure databases. This element also examines the way materials are stored, including segregation, labeling systems, and controlling stocks of cultures.<br><br>**Sub-elements**<br>6.1. Inventory<br>6.2. Information and Records<br>6.3. Transfer of Poliovirus Materials<br>6.4. Monitoring and Control | |

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| | 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:<br>j. identifying all poliovirus materials held, including cultures, specimens and other sources (e.g. infected tissues / samples or animals);<br>k. 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;<br>l. ensuring movement of poliovirus materials to and from storage meets the standards of element 15 (Transport Procedures);<br>m. ensuring the surfaces of all storage vessels are decontaminated with a validated method for inactivating polioviruses<br>n. restricting access to poliovirus materials to authorized individuals with a demonstrable legitimate need;<br>o. implementing effective physical security measures according to risk (e.g. locks, |

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| | | | alarms, access controls, etc.);<br>p. developing and maintaining a reliable sample identification system;<br>q. segregating and storing poliovirus materials according to risk;<br>r. 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 those materials. |
| | 3.2. | **Information and Records** | |
| **CWA 4.4.4.2** | 3.2.1. | Records relating to the poliovirus inventory are:<br>4. Current<br>5. Complete<br>6. Stored securely with adequate backup provision | Inventory information should include:<br>g. the name(s) of and contact information for the individuals(s) responsible for the poliovirus material and details of other personnel with access to the poliovirus materials or immediate area based on the level of the risk;<br>h. restricted access to the detailed inventory records to those individuals whose work requires access to that information;<br>i. legible and robust identification numbers and other relevant identifiers;<br>j. records of quantities / volumes of poliovirus materials (number of containers / vials or applicable equivalent),exact location of storage, and ability to account for materials at all times; |

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| | | | k. origin, including geographical source and date of collection<br>l. records of materials removed from storage to conduct work and the fate of those materials and any newly developed stocks following the completion of the work (consumed, destroyed, removed from the facility returned to storage in X location) . |
| | 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 the risk. | Controls should be set in place to ensure that all the necessary checks and documented assurances are received to ensure 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 high risk, more stringent controls including shipment tracking and verification of receipt are important considerations |
| | 3.4. | **Monitoring and Control** | |
| **CWA 4.5.3** | 3.4.1. | A review of the inventory is conducted 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 upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse. Poliovirus inventories |

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| | | | shall be monitored such 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. An inventory review shall be conducted at least annually. |
| **CWA 4.5.3** | 3.4.2. | Measures are put in place to minimize the quantities of poliovirus materials that make up the inventory. | The organization should demonstrate proactive measures towards the reduction of risk through 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 biological agents appropriate for the level of risk. |
| | | **Element 4 – General Safety**<br><br>The General Safety element examines the processes in place to make sure hazards associated with personnel's work in the facility are identified and managed while addressing their implications on biorisk. Both preventive and proactive approach should be taken to establish measures to identify, detect, mitigate, and respond to emergencies due to general safety such as fire, electrical, radiation, chemical, animal care, and pressurized equipment.<br><br>**Sub-elements**<br>4.2.General Safety | |
| | 4. | **GENERAL SAFETY** | |

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| | 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 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 potential implications for poliovirus control in such measures. Issues addressed should include but are not limited to:<br>k. general laboratory safety;<br>l. fire safety;<br>m. electrical safety;<br>n. radiation safety;<br>o. chemical safety;<br>p. use of gasses (including risk of asphyxiation);<br>q. hot work and cold work;<br>r. equipment under pressure;<br>s. laboratory animal care and use;<br>t. general housekeeping, including storage requirements and tidiness and control of general waste. |
| | | **Element 5 – Personnel and Competency** | |

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| | | The Personnel and Competency element looks at the processes in place to make sure that people with appropriate qualifications and backgrounds are recruited, that they are subsequently trained in all aspects of the work programme and their competency assessed and monitored in a structured way. Other issues addressed include the way in which capacity issues are addressed and how staff turnover is managed to ensure the organisation is not left vulnerable when critical roles are vacated.<br><br>**Sub-elements**<br>5.6. Recruitment<br>5.7. Training<br>5.8. Competence<br>5.9. Continuity and Succession Planning<br>5.10. Exclusion | |
| | 5. | **PERSONNEL AND COMPETENCY** | |
| | 5.1. | **Recruitment** | |
| **CWA 4.4.2.1** | 5.1.1. | Qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process. | Prior to taking up an appointment the organization should ensure that:<br>e. 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, etc.);<br>f. appropriate controls are implemented if existing employees are transferred to areas where there may be an increased risk profile;<br>g. all personnel who will be entering areas with potential for exposure to poliovirus materials accept compliance with the |

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| | | | healthcare standards outlined in element 9 (Healthcare), specifically including immunization with IPV every 3 years and an annual medical examination including determination of poliovirus antibody titres.<br>h. an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students, etc.), and measures 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 address:<br>g. definition of biorisk training needs, including training specific to characteristics of poliovirus and the procedures for minimizing risk within the facility, for all persons working within the containment perimeter as well as all persons who may have a need to enter the perimeter, including medical support staff, maintenance staff and emergency responders;<br>h. provision of required biorisk training;<br>i. determination of effectiveness of biorisk training;<br>j. provision of refresher biorisk training;<br>k. restrictions on personnel to ensure they do not perform tasks for which they are |

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| | | | not trained;<br>l. maintenance of adequate records<br><br>Training should include raising personnel awareness of biorisk issues including the relevance of human factors in biorisk management. |
| | 5.3. | **Competence** | |
| **CWA 4.4.2** | 5.3.1. | Personnel that 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.<br>Procedures should address:<br>f. definition of competency needs;<br>g. demonstration of successful completion of required training;<br>h. demonstration of ability to perform tasks under supervision and unsupervised;<br>i. restrictions on personnel who have not demonstrated competence to ensure they do not perform tasks for which they are not eligible;<br>j. maintenance of adequate records.<br><br>No worker should be exempt from demonstrating competence irrespective of rank, experience or background. |

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| **CWA 4.4.2** | 5.3.2. | Competence levels are judged on appropriate:<br>4. Education<br>5. Training<br>6. Experience | |
| **CWA 4.4.2** | 5.3.3. | The organization has defined required competency levels. | |
| **CWA 4.4.2** | 5.3.4 | Records are maintained verifying that staff members have attained and demonstrated those levels of competency | |
| **CWA 4.4.2** | 5.3.5. | Personnel that conduct activities within the facility are under close supervision until competency has been demonstrated. | |
| | 5.4. | **Continuity and Succession Planning** | |
| **CWA 4.4.2.3** | 5.4.1. | Adequate back-up and contingency measures are in place to address the need for continuity and succession planning. | The Organization should identify roles and individuals and ensure that 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 ensure 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 their departure or unavailability. |
| | 5.5. | **Exclusion** | |

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| **CWA 4.4.4.7.3** | 5.5.1. | Measures are set 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 procedures should address:<br>d. removal of access to the facility (e.g. removal of passes, changes of keys, access codes and other security devices, etc.);<br>e. removal of access to information relating to the facility including documentation, computerized records and data;<br>f. immediate physical removal of personnel if deemed necessary. |
| | | **Element 6 – Good Microbiological Technique**<br><br>The Good Microbiological Techniques element examines how an organization identifies appropriate microbiological techniques and controls, and how these are then implemented and reviewed. A major part of this 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.<br><br>**Sub-elements**<br>6.2. 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. | |

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| **CWA 4.4.4.5.1** | 6.1.2. | Appropriate resources (including time and equipment) are available to ensure good microbiological techniques can be adhered to effectively. | As appropriate, procedures should address risks associated with but not limited to the following:<br>l. handling of infectious poliovirus materials<br>m. animal handling;<br>n. centrifugation;<br>o. control of needles and sharps;<br>p. correct use of vacuum pumps;<br>q. culture, purification and storage techniques;<br>r. minimization / containment of aerosols;<br>s. pipetting;<br>t. sonication and other mechanical forms of cell / tissue disruption;<br>u. use of biological safety cabinets;<br>v. use of disinfectants, including spill control, routine decontamination, hand washing and showering;<br><br>This list is neither exhaustive nor comprehensive 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: |

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| | | | c. required use of devices, e.g. BSCs , which are validated to maintain primary containment for all procedures using live poliovirus<br>d. 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)**<br><br>The Clothing and PPE element examines how an organization ensures that staff is provided with the right tools to minimize potential exposures, and to make sure that they know how and when to use them. This element specifically addresses characteristics of some key items, for example use of respirators and positive pressure suits, but considers other commonly used items including gloves, laboratory coats and footwear.<br><br>**Sub-elements**<br>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:<br>i. ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback, etc.);<br>j. ensuring all personnel who have to use PPE (including scientific staff, visitors and contractors) are identified and |

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| | | | supplied with correct fitting equipment and clothing;<br>k. explicitly addressing selection and use of PPE in SOPs, training and competency assessments;<br>l. defining and conducting an appropriate programme to ensure that routine checks and maintenance of PPE are defined and carried out;<br>m. defining and addressing the need for and provision of replacement and spare PPE;<br>n. identifying and controlling the hazards associated with PPE itself (e.g. impaired dexterity or visibility);<br>o. providing adequate PPE for use during both normal and emergency working conditions;<br>p. ensuring procedures are in place for the cleaning and if appropriate the validated decontamination of used PPE including the safe storage prior to decontamination.<br><br>Personal protective equipment 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 manufacturers specifications. PPE should be made available by the employer at no cost to the |

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| | | | employee. |
| **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 on the basis of a risk assessment and may include the use of face shields, goggles, gloves, masks, HEPA-filtered respirators, 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**<br><br>The Human Factors element is critical in any biorisk management programme, addressing issues as diverse as raising awareness of biorisk issues, through initiating change management and how to measure and improve the biorisk culture within an organization. Creating an environment where people are confident in reporting what has gone wrong and eliminating blame culture are also addressed.<br><br>**Sub-elements**<br>8.2. 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 behavior, including the management of how workers interact with the facility and its equipment. | The Organization should ensure that factors associated with behaviors, and the need for individual support and communication are managed responsibly, |

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| | | | both to protect workers from direct hazards and to ensure they can function optimally within the facility. Many laboratory incidents are caused by inappropriate behavior 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.<br><br>Measures should be set in place to address:<br>k. human reliability and behavioral safety, including adherence to procedures;<br>l. team building and motivation;<br>m. communication, consultation and feedback;<br>n. conflict management and resolution;<br>o. management of stress and fatigue;<br>p. empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified;<br>q. access to counselling<br>r. avoidance of "blame culture", including willingness to report accidents, incidents or unsafe conditions / behaviours, and protection of workers who do so;<br>s. ergonomics, including equipment and work practice design to take account of |

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| | | | individual needs;<br>t. respect for individual privacy and dignity. |
| | | **Element 9 – Healthcare**<br><br>The Healthcare 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.<br><br>**Sub-elements**<br>9.4. Worker Health Programme<br>9.5. Vaccination of Personnel<br>9.6. Medical Emergencies | |
| | 9. | **HEALTHCARE** | |
| | 9.1 | **Worker Health Programme** | |
| **CWA 4.4.4.6** | 9.1.1. | The organization ensures that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to poliovirus materials, is managed effectively including prevention and protection measures. | The programme should address the needs of all individuals who may be associated with the facility, including providing assurance that contractors and visitors receive the required level of protection in line with the activities they will 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 involving all relevant personnel. | Relevant personnel that may be consulted by the programme include: |

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| | | | j. the biorisk management advisor;<br>k. the occupational health professional;<br>l. facility personnel and employee representatives;<br>m. external experts, including emergency responders;<br>n. biorisk management committee members;<br>o. veterinary and animal care facility staff;<br>p. human resources representatives;<br>q. communicable disease specialist;<br>r. scientific management.<br><br>Personnel considered to have significant risk of exposure should be identified and their healthcare needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation / testing in the event of exposure. The health including the immune status of the individual, including an assessment of polio antibody titres as described in section 9.2.3. should be considered and periodic checks as appropriate to work conditions should be established.<br><br>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. |

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| | | | These may include medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility / dexterity), the ability to use appropriate PPE safely, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status, substance abuse, etc.).<br><br>Information covered by the worker health programme should be treated in confidence. All individuals should have access to healthcare consultation either with a corporate or institutional occupational health facility or an independent health care provider, and be informed as to the nature of any treatments / vaccinations they may receive and the inherent risks and benefits of these treatments/vaccinations. |
| | 9.2. | **Vaccination of Personnel** | |
| **CWA 4.4.4.6.1** | 9.2.1. | Based on risk, the need for vaccination has been identified and covers groups identified as being potentially exposed to poliovirus. | Measures should be implemented to identify non-responders to vaccination when needed (depending on the response rate of the vaccine) 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 where there are risks of exposure. |

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| | | | Areas requiring vaccinations to enter should be posted.<br><br>Visitors, contractors and other non-core personnel should provide evidence of vaccination or evidence 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 examination of original certificates and crosschecking with medical practices responsible for administering the vaccine. The organization should ensure that the required or recommended vaccines are made available to the 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 Technique or use of PPE can be relaxed. |
| **CWA 4.4.4.6.1** | 9.2.2. | A vaccination policy has been defined and implemented. (If no, skip next question) | |
| **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 shall ensure availability of inactivated polio vaccine (IPV) for individuals associated with the facility, consistent with the objectives to:<br>d. Restrict containment facility access to individuals who have demonstrable immunity to poliovirus (defined as |

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| | | | annual verification of serum neutralizing antibody titres of 1:8 or greater against all three poliovirus types), including:<br>– Personnel assigned to work within the containment perimeter;<br>– Contractors, auditors, and visitors who have a need to enter the containment perimeter;<br>– Support personnel and contractors working immediately outside the containment perimeter (e.g. maintenance personnel, cleaning staff).<br>e. 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 on annual testing.<br>f. Provide effective secondary population safeguards by an established programme of education and promotion to encourage acceptance of immunization by:<br>– Non-core facility personnel, including contractors<br>– Worker's families/companions<br>– Other groups in contact with the facility |
| | 9.3. | **Medical Emergencies** | |

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| **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, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers. | Procedures should ensure that there is adequate emergency planning provision to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, members of the broader community and to environmental conditions that may have been affected by the incident. This should include the identification of emergency scenarios, including infected worker / family member, together with the necessary support measures (e.g. liaison with emergency services / local authorities), provision of equipment and other resources required to manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines, etc.). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained.<br><br>Procedures should ensure that adequate first aid provision is available in relation to credible accident scenarios as identified during risk assessment. The procedures should address the need for adequate provision of trained personnel and their availability, as well as equipment and other materials that may be required in the provision of treatment. |

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| | | | Procedures should ensure that additional competent medical support is identified and made available (e.g. hospitals, isolation units, etc.). |
| | | **Element 10 – Emergency Response and Contingency Planning**<br><br>The Emergency Response and Contingency Planning element examines the structures and mechanisms in place to cope with working outside the normal operating conditions and how to react proportionately to emergency situations. Issues addressed include physical requirements; capacity in terms of personnel and facilities, protective and rescue systems; emergency communications; decision making authorities, and the development and testing of emergency scenarios and simulations.<br><br>**Sub-elements**<br>10.6. Emergency Scenarios<br>10.7. Emergency Response and Planning<br>10.8. Emergency Plans<br>10.9. Emergency Exercises and Simulations<br>10.10. 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. | In order that emergency planning can take place, it is necessary to consider all credible emergency scenarios. It is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, the rationale as to why issues |

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| | | | were dismissed.<br><br>Scenarios considered should include:<br>p. infected / potentially infected worker or other contact (e.g. family member, emergency responder or community member);<br>q. accident or illness to worker within the containment area and need for evacuation;<br>r. fire;<br>s. flood;<br>t. breach of security;<br>u. explosion;<br>v. potential loss of poliovirus through theft or any other reason;<br>w. unexpected virulence (unknown biological agents or biological agents expected to be avirulent);<br>x. physical facility and equipment failure, including control system failure failure of disinfection regime;<br>y. utility failure including electricity, gas, steam and water supplies;<br>z. major spillage / aerosol release;<br>aa. environmental release;<br>bb. natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.);<br>cc. act of terrorism or deliberate vandalism, extortion;<br>dd. intense media attention. |

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| | 10.2. | **Emergency Response and Planning** | |
| **CWA 4.4.5** | 10.2.1. | Plans and procedures are established and maintained to:<br>5. Identify the potential for incidents and emergency situations involving biological agents, toxins and materials<br>6. Prevent their occurrence<br>7. Respond to emergency situations<br>8. Limit the likely 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.<br><br>A system shall be 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:<br>h. Isolating infected individuals, particularly from children and the unimmunized;<br>i. Securing collection and disinfecting stool and associated waste;<br>j. Educating families and frequent contacts on the risk posed by the poliovirus infection and procedures for isolation;<br>k. Communicating to relevant national and local officials to evaluate needs to implement community immunization response plans;<br>l. Notifying WHO;<br>m. Disinfecting areas potentially contaminated by infected individuals. | n. |
| | 10.3. | **Emergency Plans** | |
| | 10.3.1. | Biorisks are taken into account when preparing and implementing emergency plans.<br><br>A system shall be established to effectively manage incidents determined by the | The Organization should ensure that plans address as a minimum:<br>i. the identification of those responsible |

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| | | evaluation /response team as significant poliovirus exposures, including:<br>e. implementation of full preventive measures by isolating individuals under evaluation, particularly from children and the unimmunized, and securing stool and associated waste;<br>f. educating the individual under investigation, his/her family, and close contacts on the risk of poliovirus infection to the community, procedures for diagnosis, and precautionary measures necessary to prevent possible transmission;<br>g. initiating procedures to determine whether individuals are infected by collecting and testing nose, throat, and stool specimens daily for a minimum of 7 days post exposure.. | for devising, implementing and testing the control measures specified along with the communication and evaluation to all relevant personnel of competence in response;<br>j. the legality and enforceability of proposed emergency response plans<br>k. the need to respond during out-of-hours emergencies as well as those that occur during normal working hours;<br>l. provision for periods of reduced staff availability (e.g. during weekends and holiday periods);<br>m. the need for emergency access / exit, including the ability to override access controls as appropriate;<br>n. the need for emergency exit routes to avoid evacuating people through areas of higher biosafety or biosecurity;<br>o. the provision for safe removal, transport, transfer, treatment and accommodation of contaminated persons, objects;<br>p. the need to inform visitors and contractors of emergency response plans and the possible consequences of exposure.<br><br>h. |
| **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. | |

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| **CWA 4.4.5.2** | 10.3.3. | Emergency plans are effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations. | In the event of an emergency situation there may be a requirement to involve parties external to the organization. Based upon the credible scenarios identified, the organization should identify 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 as to their role and any risk exposures they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency (e.g. uncontrolled use of fire water). Contact information should be documented and made available to personnel responsible for coordinating the emergency response activity.<br><br>External agencies consulted may include:<br>h. police and security services;<br>i. fire services;<br>j. ambulance and local hospitals / healthcare providers;<br>k. transport providers / couriers;<br>l. local and national government officials;<br>m. environmental authorities;<br>n. WHO. |
| | 10.4. | **Emergency Exercises and Simulations** | |

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| **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 in order to provide an assurance that plans are effective and to learn from any lessons that arise.<br><br>Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. 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 the exercise should be documented and reviewed for lessons learnt, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, allocated to named individuals and measures set 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. | In the event of an emergency or unforeseen event there may be disruption to normal operating conditions. This could range from the need to safely shut down work in the event of a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively and contingency plans set in place. Activities should address |

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| | | | 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 failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shut down of operations in extreme situations. |
| | | **Element 11 – Accident / Incident Investigation**<br><br>The Accident/ Incident Investigation element addresses activities directed toward defining the facts and circumstances related to the event, determining the causes, and developing remedial actions to control the biorisk and prevent future 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 the consequences of the accident 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.<br><br>**Sub-elements**<br>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, analyze and learn from accidents and incidents involving poliovirus materials. | Procedures should be set in place to ensure that what constitutes an accident or incident is clearly defined and |

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| | | | communicated to all relevant personnel, and may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed, and it is essential that lessons are learned and improvements are made where possible.<br><br>As a minimum, the accident / incident investigation process should include:<br>m. creating a culture of self-reporting of incidents, including "near misses" in addition to incidents that may trigger an investigation or emergency response;<br>n. identifying those responsible for maintaining the accident / incident reporting system;<br>o. 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);<br>p. defining what constitutes a significant poliovirus exposure (e.g., ingestion) and thresholds for initiating procedures to determine whether individuals are infected;<br>q. specifying required documentation to support the system, frequency and |

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| | | | distribution of reports generated, and communicated to relevant personnel;<br>r. identifying the reports that will be generated, their frequency and distribution;<br>s. 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.<br>t. establishing and publicizing 24 hour accident / incident reporting channels, identifying those responsible for maintaining the system;<br>u. ensuring analysis of trends;<br>v. identifying root causes using individuals trained in investigation techniques;<br>w. providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learnt result in action to avoid the repeat of such events and / or minimize their potential impact;<br>x. identifying where security professionals may be required to coordinate with law enforcement. |
| | | **Element 12 – Facility Physical Requirements** | |

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| | | The Facility Physical Requirements element looks at how the organization addresses biorisk during periods when something new is introduced or the existing setup is changed. Issues addressed include the people who need to be involved and consulted, how biorisk is incorporated into planning, the need to address commissioning in a structured way (including the role of suppliers), the physical characteristics of the materials used and any certification that may have to be carried out.<br><br>**Sub-elements**<br>12.4. Planning, Design and Verification<br>12.5. Commissioning and Decommissioning<br>12.6. 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 upon 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 needs of the facility are determined through risk assessment. Engineering and operational solutions shall be incorporated that are consistent with the risk posed by the properties of materials that will 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 Biosafety Manual, 3rd ed.), industry good practices and facility-specific risk assessments. | The design process should include the identification and review of relevant legislation and codes of practice (including building codes as well as those relating to laboratory biosafety / laboratory biosecurity) and risk assessments. The requirements |

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| | | | identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and the standards of acceptance to assure performance. The process should be documented and transparent to provide an assurance that it has been comprehensive and thorough. |
| **CWA 4.4.4.8.1** | 12.1.3. | The design process identifies and consults all relevant parties associated with the facility and its operation. | The design process should include the identification of and consultation with individuals involved in planning, construction, operation and maintenance of the facility.<br><br>The following roles / individuals should be considered in terms of information requirements and need for consultation:<br>n. scientific personnel and other end users;<br>o. biorisk management advisor, biorisk management committee;<br>p. biosecurity and / or security personnel;<br>q. designers (architects and engineers);<br>r. constructors;<br>s. maintenance engineers;<br>t. materials and equipment suppliers;<br>u. commissioning agents;<br>v. certifiers;<br>w. regulators;<br>x. WHO |

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| | | | y. first responders;<br>z. other relevant parties identified in risk assessments.<br><br>If justified, based on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specification<br>4. is in line with accepted good practice;<br>5. incorporates features capable of providing assurance for control of poliovirus materials;<br>6. ensures relevant legislative requirements, and, standards, and risk assessment findings have been incorporated into 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 specification. | |
| **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. | There is a formal process for:<br>3. Initial commissioning of new facilities<br>4. Final decommissioning of existing ones | Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase at the first stage of science programme definition to assure that |

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| | | | the expectations for the building are achievable. The commissioning plan should develop in detail in parallel with the physical concept to assure that the expectations for the building are measurable. The commissioning plan should clearly identify, with examples, all steps from beginning to end including conditions of acceptance of each step, as a pre-requisite of proceeding to the next.<br><br>The commissioning plan should identify all steps required before operation is commenced initially or resumed after 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.<br><br>The decommissioning process should identify the decontamination procedures and security-related measures that have to be in place for temporary or final shut down of the facility. The de-commissioning programme should not only describe the procedures to be undertaken, but also, the standards of acceptance when those procedures are performed.<br><br>This may be documented through clearance certificates and permits to work, |

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| | | | 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.<br><br>The poliovirus facility shall incorporate features that are guided by assessment of the risk of poliovirus reintroduction to the community and include the following provisions:<br>k. Poliovirus facilities are located in countries with demonstrated high national immunization coverage (= DPT3 coverage);<br>l. Poliovirus facilities are located in areas with closed sewage systems with secondary or greater treatment of effluents<br>m. 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;<br>n. 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.<br>o. The use of devices (e.g. BSCs) which 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 normal operation of the BSC (i.e. showering out not required when class III BSC is functioning properly).<br>p. 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.<br>q. Controlled exit from the containment perimeter is via a walk-through exit shower. | |

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| | | 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).<br>r. 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 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.<br>s. Throughout the Poliovirus type 2 containment period, a dose of IPV will be introduced, high global vaccine coverage will be maintained, a dose of IPV will be introduced, population immunity is not expected to decline, and the use of mOPV2 for outbreak response is considered. Where evidence of satisfactory implementation of primary and secondary safeguards (described in GAPIII) is provided, decontamination of effluents is not required.<br>t. Decontamination of all materials exiting the facility is achieved through a validated sterilization / decontamination procedure. Examples include:<br>– 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<br>– A material airlock / decontamination chamber sealable for gaseous decontamination;<br>– A dunk tank containing sufficient active compound to inactivate poliovirus.<br><br>The poliovirus animal facility shall incorporate features guided by risk assessment as described above and shall meet all poliovirus containment criteria as described in this document including:<br>i. compliance with containment criteria for animal facilities that are consistent with the controls outlined in other sections of this document;<br>j. special training and supervision of personnel responsible for inoculating, harvesting, sampling, animal autopsies, and any other manipulations with poliovirus infected animals; | |

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| | | k. the use of devices (e.g. BSCs) which are validated to maintain primary containment is required for all animal manipulations with live poliovirus;<br>l. housing infected animals separately;<br>m. maintaining barriers to prevent escape of infected animals;<br>n. maintaining accurate records and accounting for all infected animals;<br>o. meeting international criteria for laboratory animal care;<br>p. security procedures specific for facilities housing animals involved in biomedical research | |
| | | **Element 13 – Equipment and Maintenance**<br><br>The Equipment and Maintenance element aims to make sure that all equipment which may have implications for control is selected with biorisk taken into consideration. Emphasis is placed upon selection procedures, maintenance of asset registers, control over where the equipment may be moved to and what it will be used for throughout its working life. Particular attention is also given to making sure the equipment functions properly by following prescribed periodic and predictive maintenance, supported by adequate breakdown response.<br><br>**Sub-elements**<br>13.6. Maintenance Management<br>13.7. Control of Equipment<br>13.8. Calibration<br>13.9. Certification<br>13.10. 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 impact on biorisk is maintained in a manner | The maintenance programme should apply to all aspects of the physical structure |

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| | | consistent with the intent and requirements of the biorisk management programme. | (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.<br><br>In planning and conducting maintenance activities the organization should consider:<br>k. adequately maintaining the physical integrity of the facility and its fixtures and fittings;<br>l. ensuring maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment;<br>m. ensuring adequate controls are in place to prevent workers being exposed to poliovirus in the course of their work<br>n. identifying and recording maintenance requirements at time of construction of facilities, or purchase / acquisition of equipment;<br>o. creating and maintaining a maintenance register for all applicable equipment;<br>p. identifying and conducting planned maintenance activities at an appropriate frequency;<br>q. ensuring adequate provision for |

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| | | | unplanned (breakdown) maintenance to ensure integrity of the facility is maintained at all times;<br>r. determining and monitoring predictive maintenance requirements and associated indicators and monitors;<br>s. ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement;<br>t. 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 impact on biorisk is 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:<br>f. identifying equipment in line with identified work needs, which can be demonstrated as fit for purpose;<br>g. controlling purchase / acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel;<br>h. controlling entry and exit of equipment to and from the poliovirus facility, including decontamination requirements (e.g. air locks and decontamination)<br>i. ensuring the asset register is regularly updated<br>j. ensuring stocks and supplies of |

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| | | | 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 impact on biorisk is 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:<br>f. identifying and recording calibration requirements at time of purchase / acquisition;<br>g. identifying the standards / tests that will be used to ensure the equipment is correctly calibrated;<br>h. establishing procedures to conduct calibrations on equipment used in live virus areas<br>i. creating a documented and up-to-date calibration register for all applicable equipment;<br>j. ensuring calibration is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment. |
| | 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 impact on biorisk is 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:<br>d. identifying and recording certification requirements at time of purchase / acquisition of equipment, including relevant and current standards against |

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| | | | which to certify;<br>e. ensuring competent and independent certifiers are used for the certification process;<br>f. ensuring certification is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment. |
| | 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 impact on biorisk is 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:<br>f. identifying and recording validation requirements at time of purchase/acquisition;<br>g. identifying the standards/tests that will be used to ensure the equipment is correctly validated;<br>h. creating a documented and up-to-date validation register for all applicable equipment;<br>i. ensuring validation is scheduled and conducted in the line with manufacturer's requirements and / or other specified intervals as identified by risk assessment;<br>j. ensuring competent and independent validation parties are used for the validation process. |

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| | | | For physical security systems, the analogous concept is performance testing; evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed. |
| | | **Element 14 – Decontamination, Disinfection and Sterilization**<br><br>The Decontamination, Disinfection and Sterilization element examines the controls in place to ensure that appropriate disinfection, decontamination and sterilization routines are in place to manage the risk presented by the organisms and work activities undertaken. The element addresses general requirements for procedures, training and waste disposal but also looks at more specific issues including the potential need for specialist laundering and issues specific to animal facilities.<br><br>**Sub-elements**<br>14.3. Management of Biological Waste<br>14.4. Inactivation of Biological Agents and Toxins | |
| | 14. | **DECONTAMINATION, DISINFECTION AND STERILISATION** | |
| | 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.<br><br>No viable poliovirus shall 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 shall be identified and adequate prevention measures set 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:<br>f. ensure programme is in place to minimize the waste production;<br>g. ensure effective waste audit trails are in |

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| | | | place and documented;<br>h. provide adequate facilities and procedures for the storage of waste (including short term storage);<br>i. ensure methods are available for effective segregation and decontamination of mixed waste (e.g., infected animals that have received radioactive materials);<br>j. 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:<br>3. Identified<br>4. Documented | Sources of contamination that should be considered include:<br>q. personnel;<br>r. clothing and PPE;<br>s. glassware;<br>t. equipment;<br>u. cultures and associated materials;<br>v. spill clean-up materials and equipment;<br>w. possibly infectious microorganisms and toxins and contaminated materials;<br>x. paper and plastic waste;<br>y. needles, syringes and sharps;<br>z. waste water, including that from sinks and showers;<br>aa. air;<br>bb. filters and air handling systems;<br>cc. discarded equipment used in the facility; |

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| | | | dd. animals exposed to laboratory poliovirus;<br>ee. animal carcasses and bedding;<br>ff. facilities.<br><br>All potential waste streams and other sources of contamination should be identified and documented.<br><br>For each of these sources, procedures should be put in place to validate the decontamination regime and records shall demonstrate that no contaminated persons / materials leave the facility and inactivation measures have been implemented effectively. |
| **CWA 4.4.4.5.2** | 14.1.3. | Effective 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 it may be necessary to hold contaminated dedicated equipment such as fire fighter apparel or ambulance tools on site if they cannot be effectively decontaminated.<br><br>Risk assessment should be an integral part |

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| | | | 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 that appropriate methods for disinfection and decontamination are chosen and implemented effectively.<br><br>Procedures shall be established, validated, and maintained for effective poliovirus decontamination of the facility.<br><br>Inactivation of Poliovirus. Procedures shall be established and maintained to ensure complete inactivation of all poliovirus from all materials and solid waste streams leaving the containment perimeter such that<br>j. Heat sterilization (autoclaving) shall be the preferred method of inactivation of poliovirus;<br>k. SOPs are available to address both routine and non-routine activities (e.g. daily routines vs. major spills);<br>l. SOPs are developed to respond to failure of decontamination procedure or equipment<br>m. SOPs are validated and shown to be effective against poliovirus prior to their use;<br>n. All materials leaving the containment perimeter (including clothing liquid / solid waste) are heat sterilized or subject to chemical treatment of proven effectiveness prior to removal;<br>o. All material leaving the containment perimeter is accompanied by documentation of its decontamination<br>p. Resources are available to deal with emergencies, accidents, and other incidents;<br>q. In the event that live poliovirus is to be removed from the facility this will be done through use of a dunk tank, decontamination chamber or other validated mechanism that ensures disinfection of the exterior surfaces of any packaging materials used;<br>r. The facility inactivates all waste and other potentially contaminated material before it is passed to contractors or other third parties for waste disposal. | Whatever the poliovirus materials handled, it is likely that a number of effective inactivation methods will be available. The organization should ensure that there are data 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 issues including;<br>e. the nature of the material being treated (e.g. volume, presence of protein / other potentially inhibitory substances;<br>f. contact times, materials compatibility issues (e.g. interaction with stainless steel or rubber seals):<br>g. potential health hazards associated with the disinfectant;<br>h. the need to maintain the required level of active compound, including deterioration over time.<br><br>In planning and conducting decontamination activities the organization should consider:<br>ix ensuring all disinfectants used contain sufficient active compound to address |

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| | | | the working conditions under which they will be applied, and that such concentrations are maintained throughout the process, including conducting specific validation activities where necessary;<br>x providing adequate facilities and procedures for the storage of waste (including short term storage);<br>xi ensuring methods are available for effective decontamination of mixed waste (e.g., infected animals that have received radioactive materials);<br>xii ensuring that where appropriate, methods are available for decontamination of sensitive equipment or that which is not suitable for autoclaving (e.g. computers);<br>xiii implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and use of indicators in autoclaves);<br>xiv decontaminating protective clothing by appropriate means prior to leaving the facility;<br>xv ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside the facility;<br>xvi implementing programmes to ensure |

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| | | | the amount of contaminated waste is minimized. |
| | | **Element 15 – Transport Procedures**<br><br>The Transport Procedures element explores how an organization deals with issues associated with internal and external transport of biological materials, and looks at the necessary roles and responsibilities, materials and equipment, including the need to work with specialist couriers and shipping agents.<br><br>**Sub-elements**<br>15.2. 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:<br>i. ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines;<br>j. ensuring internal transport of poliovirus (within the facility, but outside the containment perimeter) meets equivalent biosafety and biosecurity standards required for external transport outside the facility;<br>k. ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used |

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| | | | as part of the transportation process;<br>l. selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely;<br>m. whether a request for poliovirus materials is being made by an approved facility for a legitimate reason, and equivalent controls are applied to importation of material to the facility;<br>n. the need is identified for formal documented transfer forms signed by the responsible management representative authorizing movement of materials.<br>o. document control that allows traceability of material movements;<br>p. identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation of poliovirus materials, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off. |
| | | **Element 16 – Security**<br><br>The Security element examines how an organization manages security with regard to biorisk. The element looks at some of the more obvious issues like access control, but also the need for information security and support from external agencies. | |

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| | | **Sub-elements**<br>16.6. Physical Security<br>16.7. Information Security<br>16.8. Personnel Control<br>16.9. Personal Security<br>16.10. Contractors, Visitors and Suppliers | |
| | 16. | **SECURITY** | |
| | 16.1. | **Physical Security** | |
| **CWA 4.4.4.8.4** | 16.1.1. | Controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained. | Measures should be set 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.<br><br>In planning and conducting security risk assessments the organization should consider:<br>n. theft or diversion of poliovirus materials or related equipment, documents or data;<br>o. sabotage including vandalism and tampering;<br>p. break-in and intrusion;<br>q. labour issues and disputes;<br>r. kidnapping and extortion;<br>s. weather-related emergencies (i.e., |

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| | | | earthquake, tsunami, flood, tornado, and hurricane);<br>t. workplace violence;<br>u. utilities failure;<br>v. picketing, occupation and barricade;<br>w. screening and isolation of suspect packages;<br>x. acts of terrorism;<br>y. civil unrest or war;<br>z. cyber threats .<br><br>Care should be taken to coordinate biosecurity measures with those of biosafety to manage and minimize conflicting priorities.<br><br>Breaches of security should be reported, recorded and investigated as accidents and incidents.<br><br>Procedures for the physical security of poliovirus materials including cultures, specimens, samples and potentially contaminated materials should be implemented and maintained such that:<br>h. The containment facility shall be located on a secure site with perimeter control to discourage unauthorized access;<br>i. The containment facility shall be located away from uncontrolled traffic flows and entrance shall be via a |

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| | | | locked door with two-factor access control measures (e.g. requirement for electronic pass with personal access code);<br>j. During poliovirus manipulations, a second person within the containment perimeter or in close proximity should be aware of the work being conducted and available for contact if needed;<br>k. The perimeter of the facility shall be subject to constant monitoring, e.g. the use of alarms, security personnel and closed circuit TV;<br>l. Measures shall be implemented to identify and record all personnel in the facility at any point in time<br>m. Anti-intrusion alarms and sensors shall be installed including interfaces with police and other security services;<br>n. Panic buttons and 'silent' emergency alert measures shall be 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 is 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 unauthorized release of such information are critical. |

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| | | | Procedures addressing information security should consider:<br>f. 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;<br>g. computer security including robust internet firewalls and encryption protocols;<br>h. strict policies regarding PC's, laptop computers, storage media, cameras, etc. entering or leaving the facility;<br>i. thorough destruction of paper files to be discarded and complete erasure of unwanted electronic files;<br>j. security measures and procedures |
| **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 personnel reliability assessment measures required should be determined as part of the risk assessment process. The organization shall ensure that access to poliovirus containment areas is limited to personnel |

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| | | | that have been screened for subversive behaviors / associations or criminal records or are accompanied at all times by authorized individuals (as in the case of visitors, contractors, etc.). The screening includes:<br>• Association with organizations that could present a threat to integrity of the facility;<br>• Medical conditions that could lead to unstable / undesirable behavior;<br>• Providing assurance that individuals do not work under the influence of drugs or alcohol. |
| **CWA 4.4.4.7.1** | 16.3.2. | The organization shall ensure that access to facilities or work is controlled for individuals according to the policy. | Where lawful and appropriate as determined by risk assessment, screening may include such checks as identity and immigration status, membership of 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 that include, where appropriate, personal security awareness training.<br><br>Documented security drills and exercises shall be 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** | |

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| **CWA 4.4.4.7.2** | 16.5.1. | The organization ensures that suppliers, contractors, visitors and sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility. | |

# 4. International certification of essential poliovirus facilities

1. Definitions
2. Purpose
3. International standards
4. Criteria for certification
5. Steps of the procedure
6. Monitoring
7. Reassessments
8. Confidentiality
9. Fees
10. Conflicts of interest

## *1. Definitions*

See Annex 1

## *2. Purpose*

This annex sets forth the policy for international certification of essential poliovirus facilities as described in the *WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of routine OPV use (GAPIII)*.

## *3. International standards*

WHO, establishes the standards and requirements for certification guided by the following general principles:

- Physical facilities and biosafety practices meet all published national and WHO primary safeguards of facility containment and tertiary safeguards of location (*GAPIII, Annexes 2 and 3)*.

- Persons qualified by competence and experience direct all laboratory operations.

- Supervisory personnel and staff at all administrative levels are informed of the national, institutional, and laboratory responsibilities inherent to working with polioviruses.

## *4. Criteria for international certification*

The poliovirus facility and its administrative entity must be nominated by the Minister of Health or designated national authority for international certification and declared to meet all biorisk management criteria consistent with international standards (Annexes 2 and 3).

### *5. Steps of the procedure*

(a). Official request: The senior manager of the facility applies to the Ministry of Health or designated authority for international certification. Facilities must be fully operational. Applications must provide evidence of meeting requirements defined in GAPIII (Annexes 2 and 3)..

(b). Evaluation of application: The national authority determines whether the application is in the national interest, whether the facility qualifies as certifiable, and whether the information requirements are met. The national authority nominates the qualifying facility for international certification and submits an application through the WHO Regional Office to WHO. Separate applications must be submitted for each facility..

(c). Site visits and auditors: Facilities are evaluated on-site by a team of at least two auditors selected by WHO from an international roster of qualified professionals and agreed to by the Minister of Health or other designated responsible national authority. Site auditors must be permitted to enter all laboratory and storage facilities related to operation of the facility and have access to all relevant laboratory programmatic information, protocols, and records. Site auditors must respect and adhere to facility biorisk management policies and procedures, including showering out and wearing protective clothing.

(d). Reports and outcome: The international certification office reviews national applications and site visit reports and recommendations, makes final determination on certification status of individual facilities, and informs the national authority of its findings.

### *6. Monitoring*

Certification is granted contingent upon favourable annual national audits, reports submitted by the national authority to WHO, and international on-site visits, where necessary, at three year intervals. Additional interim visits may be required to confirm corrections of deficiencies or review modifications or changes in programme or facilities. Interim or follow-up on-site visits may require only one reviewer.

### *7. Reassessments*

Once granted, international certification may be revoked by either the designated national authority or WHO upon due cause of adverse changes in facility operations or structure. The Ministry of Health or other designated national authority must be notified in writing of the decision to withhold or revoke facility certification. Depending upon the nature of the infraction, the certified facility may be given additional time (up to 12 months) to correct deficiencies before final revocation. Appeals to WHO to restore facility certification are accepted only from the designated national authority.

### *8. Confidentiality*

Site auditors must keep all information confidential and disclose findings and recommendations only to WHO. All WHO files and records of certification shall be held in confidence.

### *9. Fees*

Facilities applying to national authorities for international certification shall expect to support costs associated with the certification process.

### *10. Conflict of interest*

Site reviewers 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 (DoI) must be on file in WHO.

# 5. Risk assessment strategy