Policy for Emergency Response and Exposure Management Plans at U.S. Poliovirus-Essential Facilities

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NAC
U.S. NATIONAL AUTHORITY
FOR CONTAINMENT OF POLIOVIRUS

U.S. DEPARTMENT OF
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Contents

1. Purpose

The U.S. National Authority for the Containment of Poliovirus (NAC) requires poliovirus-essential facilities (PEFs) to develop, implement, and maintain comprehensive emergency response plans and procedures, encompassing all containment and facility programs applicable to incidents occurring in the poliovirus (PV) containment area(s). The U.S. NAC *Policy for Emergency Response and Exposure Management Plans at U.S. Poliovirus-Essential Facilities* applies to U.S. PEFs seeking an Interim Certificate of Containment (ICC) or a Certificate of Containment (CC) [i], outlining requirements and guidance to establish and maintain emergency response plans and procedures that "1. identify the potential for incidents and emergency scenarios involving biological agents, toxins, and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them." [*GAPIII subelement 10.2.1*] Emergency response is essential to a successful PV containment program to reduce the likelihood, frequency, and severity of emergencies and calamitous events occurring at a PEF. This U.S. NAC policy is intended to support and not replace the World Health Organization's (WHO) Global Action Plan, 3rd Edition (GAPIII) or WHO Public Health Management of Facility Related Exposure to Live Polioviruses. Poliovirus-essential facilities are responsible for implementing all measures required in these documents, including measures not addressed specifically in this policy. Poliovirus-essential facilities may consider additional measures to mitigate the potential for emergencies in PV containment area(s).

2. Scope

The following statements apply to this policy:

- **Only U.S. facilities that possess or are in pursuit of a Certificate of Participation (CP) [i] issued by the U.S. NAC may be in possession of or receive wild PV/vaccine-derived PV (WPV/VDPV) type 1 infectious materials (IM).** U.S. facilities with oral polio vaccine (OPV) PIM should consider the WHO PIM Guidance document while facilities with WPV PIM should review the U.S. NAC *Interim Guidance for U.S. Laboratory Facilities to Store and Work with Poliovirus Potentially Infectious Materials*.
- **U.S. facilities in possession of WPV/VDPV types 2 and 3 IM, as well as OPV type 2 IM must implement GAPIII and apply for an ICC.**
- The U.S. NAC interprets WHO containment requirements and guidance from GAPIII, Public Health Management of Facility Related Exposure to Live Polioviruses, and other documents. With the assistance of an external working group and feedback from the affected PEFs, the U.S. NAC creates policies for implementing specific aspects of PV containment in the U.S.
- U.S. NAC policies are subject to modification depending on external circumstances such as the global polio epidemiological situation, vaccination coverage, new international policies, or changes to eradication status.
- U.S. NAC policies excerpt information from GAPIII, shown in quotations, and/or include a reference to GAPIII elements or other materials, where applicable.
- The terms: a) "shall" or "must" indicate a requirement; b) "should" or "consider" indicate a recommendation; c) "may" indicates a permission; d) "can" indicates a possibility or a capability.

3. Acronyms

Acronym	Definition
CC	Certificate of Containment
cDNA	Complementary (or copy) deoxyribonucleic acid
cVDPV	Circulating vaccine-derived poliovirus
CP	Certificate of Participation
GAPIII	Global Action Plan III
GPLN	Global Polio Laboratory Network
HVAC	Heating, ventilation, and air conditioning
ICC	Interim Certificate of Containment
IM	Infectious materials
IPV	Inactivated polio vaccine
NAC	National Authority for Containment of Poliovirus
OHP	Occupational Health Program
OPV	Oral polio vaccine
PAPR	Powered air purifying respirator
PCR	Polymerase Chain Reaction
PEF	Poliovirus-essential facility
PIM	Potentially infectious materials
PPE	Personal protective equipment
PPLB	CDC, Polio and Picornavirus Laboratory Branch
PV	Poliovirus
RNA	Ribonucleic acid
SL	Sabin-like PV
VDPV	Vaccine-derived poliovirus
WHO	World Health Organization
WPV	Wild poliovirus

4. Definitions

Term	Definition
Accident/Incident	Confirmed PV containment or PV work-related event which results in the following: Injury (*e.g.,* hernia from lifting heavy objects inside PV containment) Exposure or illness Breach of containment Other events resulting in property damage or disruption of facility operations Accidents/incidents hereinto referred to as incidents.
Biorisk	"Risk relating to biosafety and biosecurity where the principal hazard is a biological agent (in the case of this standard, poliovirus)." [ii] Please see the U.S. NAC *Biorisk management and risk assessment* policy for additional information.
Circulating VDPV	VDPV isolates for which there is evidence of person-to-person transmission in the community.

Term	Definition
Exposure	"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 membrane." [ii] "Community members may be exposed to infectious agents from the laboratory through (1) workers' contaminated skin or clothing or unrecognized infection; (2) the release of contaminated air; (3) contaminated effluents and waste water recovered from secondary sewage treatment plants; (4) the uncontrolled transport of infectious material; (5) solid waste transported to landfills; (6) contaminated equipment or materials removed from the facility; (7) the escape of infected animals; and (8) a theft or deliberate release of infectious agents from a facility." [ii]
Global Action Plan III	The WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use (GAPIII). The 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 and the 2nd edition of the WHO global action plan for laboratory containment of wild polioviruses.
Inactivated Poliovirus Vaccine	The inactivated poliovirus vaccine was developed in 1955 by Salk and Youngner [iii]. IPV is a killed-virus vaccine and is administered by injection.
Infectious materials	WPV/VDPV "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 transgenic mice; Derivatives produced in the laboratory that have capsid sequences from wild polioviruses [1], unless demonstrably proven to be safer than Sabin strains. The safety of new derivatives containing wild poliovirus capsid sequences will be assessed by an expert panel [2], on the basis of comparison to reference Sabin strains for (i) degree and stability of attenuation; (ii) potential for person-to-person transmission; and (iii) neurovirulence in animal models; Cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus [3]." [ii] OPV/Sabin "Cell culture isolates and reference OPV/Sabin strains;

[1] For U.S. facilities, PV derivatives must contain a complete full-length WPV capsid sequence to meet the WPV IM definition.

[2] Expert panel will be determined by WHO.

[3] For U.S. facilities, PV strains must contain a complete full-length WPV capsid sequence to meet the WPV IM definition.

Term	Definition
	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; Fecal or respiratory secretion samples from recent OPV recipients; Infected animals or samples from such animals, including poliovirus receptor transgenic mice; Derivatives produced in the laboratory that have capsid sequences from OPV/Sabin strains [4]; Cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains [5].” [ii]
Isolation	“Separation of infected or contaminated persons, i.e., the person who has been directly exposed to a PV.” [iv]
Oral polio vaccine /Sabin	“Attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains).” [ii] Also called ‘Sabin vaccine’, OPV contains live, attenuated (weakened) poliovirus strains. OPV formulations include: Trivalent OPV (tOPV) contains all three serotypes of Sabin strains (1 + 2 + 3); use of tOPV ended in April 2016 Bivalent OPV (bOPV) contains Sabin strains 1 + 3; as of April 2016, only bOPV is used routinely Monovalent OPV (mOPV) contains only one serotype of Sabin strain
Near Miss	“A near-miss is a potential hazard or incident in which no property was damaged, and no personal injury was sustained, but where, given a slight shift in time or position, damage or injury easily could have occurred. Near misses also may be referred to as close calls, near accidents, or injury-free events.” [v]
Nucleic acids	Full-length “poliovirus RNA, cDNA and total nucleic acid extracted from poliovirus infectious materials (*e.g.,* a virus isolate) or potentially infectious materials (*e.g.,* stool, respiratory specimen, sewage) using methods demonstrated to inactivate poliovirus, or synthesized RNA or cDNA (*e.g.,* cDNA clone, synthetic transcript). Poliovirus nucleic acid can be handled outside of poliovirus containment under the condition that these materials will not be introduced into poliovirus permissive cells or animals (as defined in GAPIII and in the “Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses”) with or without a transfection reagent, except under appropriate containment conditions as described in GAPIII Annex 2 or Annex 3.” [vi] **Note: WHO has exempted full-length PV nucleic acids from GAPIII containment. However, WHO does require that full-length PV nucleic acids are included as part of the facility and national inventories.**
Personal Protective	“Equipment and/or clothing worn by personnel to provide a barrier against

[4] For U.S. facilities, PV derivatives must contain a complete full-length OPV/Sabin capsid sequence to meet the OPV/Sabin IM definition.

[5] For U.S. facilities, PV strains must contain a complete full-length OPV/Sabin capsid sequence to meet the OPV/Sabin IM definition.

Term	Definition
Equipment	biological agents, thereby minimizing the likelihood of exposure. PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators." [vii]
Poliovirus	A picornavirus consisting of three serotypes: 1, 2 and 3; protective immunity is type-specific. Poliovirus serotypes are further subdivided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines). Poliovirus types 2 and 3 have been eliminated in the wild. In this current stage of polio eradication, only type 1 wild poliovirus continues to circulate in endemic areas. It is highly infectious and causes paralytic polio.
Poliovirus containment area	Poliovirus-essential facility area(s) listed on the PEF CP application. Infectious materials of OPV2 IM and WPV/VDPV of all three serotypes cannot leave containment area(s) without a transport container or have been inactivated using a validated method. Access to PV containment area(s) must be limited to essential personnel only.
Poliovirus- essential facility	"A facility designated by the ministry of health or another designated national body or authority as serving critical national or international functions that involve the handling and storage of needed poliovirus infectious materials or potentially infectious materials under conditions set out in this [GAPIII] standard." [ii] U.S. PEFs will possess or be in pursuit of a CP.
Poliovirus Breach	"A release from a PEF of a PV subject to containment." [iv]
Poliovirus Exposure	Any facility accident or incident that potentially exposes humans to any PV through ingestion, inhalation, or skin contact.
Potentially infectious materials	"Fecal or respiratory secretion samples and their derivatives (*e.g.* stool suspensions, extracted nucleic acids, etc.) collected for any purpose in a geographic area where WPV/cVDPV is present or OPV is being used at the time of collection; Products of such materials (above) from PV-permissive cells or experimentally infected polio-susceptible animals; Uncharacterized enterovirus-like cell culture isolates derived from human specimens from countries known or suspected to have circulating WPV/VDPV or use of OPV at the time of collection; Respiratory and enteric virus stocks derived from PV PIM and handled under conditions conducive to maintaining the viability or enabling the replication of incidental PV; and Environmental samples (*i.e.,* concentrated sewage, wastewater) collected from areas known or suspected to have circulating WPV/VDPV or use of OPV at the time of collection." [viii]
Poliovirus materials	Unless a serotype is specifically identified, PV materials refer to IM and PIM of all three PV serotypes.
Quarantine	"Separation of contacts from individuals who have been exposed to PV directly, to pre-emptively remove the risk of further transmission." [iv]
Sabin-Like Poliovirus	"Any poliovirus isolate from human or environmental sample with any nucleotide difference from Sabin less than the number that meets the definition of a VDPV" (*i.e.,* less than 1%). [ix]
Vaccine derived	Classified with wild polioviruses and usually demonstrate 1–15% sequence

Term	Definition
poliovirus	differences from the parental OPV strain; they may have circulated in the community (cVDPV) or have replicated for prolonged periods in immunodeficient subjects (iVDPV) or be ambiguous and of unknown origin (aVDPV).

5. Planning for Incidents and Emergencies at Poliovirus-Essential Facilities

Poliovirus-essential facilities must ensure that emergency response plans and procedures protect the health and safety of facility personnel, visitors, and the public surrounding the facility. Strong and effective emergency response plans and procedures are crucial to program-wide continuous quality improvements that reduce the likelihood and severity of emergencies and enhance the safety of the individuals and community associated with the PEF.

Poliovirus-essential facilities should create and encourage a culture conducive to self-reporting incidents, including "near misses", to ensure investigations and emergency responses occur timely and appropriately. [*GAPIII subelement 11.1.1 guidance*] Accordingly, comprehensive PEF emergency response plans and procedures must implement all appropriate GAPIII elements [*GAPIII subelement 10.2.2*] as well as WHO Public Health Management of Facility Related Exposure to Live Polioviruses and U.S. NAC policies to mitigate the potential for emergencies occurring in PV containment area(s). Please see the U.S. NAC *Policy for Poliovirus Occupational Health Programs at U.S. Poliovirus-Essential Facilities* for additional information on establishing health surveillance and vaccination programs.

Poliovirus-essential facility plans and procedures must be "reasonable and proportionate to the scale and nature of the emergency" [*GAPIII subelement 10.3.2*]. For example, a Low Risk event (*e.g.,* needlestick) could involve facility, local and/or state resources with U.S. NAC notification and consultation while a Very High Risk event (*e.g.,* disposal of PV-contaminated waste into laboratory sink without appropriate decontamination) could require local and/or state health agencies, U.S. NAC, Centers for Disease Control and Prevention (CDC), and WHO engagement and technical assistance (See Managing PV Exposures below). Poliovirus-essential facilities must tailor plans and procedures according to their containment program. Emergency response plans and procedures must also ensure that "biorisks are taken into account" [*GAPIII subelement 10.3.1*] including personal, public health, security, and environmental hazards associated with PV materials.

Poliovirus-essential facilities must educate and train essential, medical, and external partner personnel who may be involved in PV-related emergency responses. [*GAPIII subelement 9.3.1 guidance*] Poliovirus-essential facilities should train personnel periodically (*e.g.*, annual or following significant procedural changes) and document training including curriculum and methods used to verify understanding. Emergency procedures training must be provided to visitors and non-essential personnel who enter PV containment area(s) to ensure procedural awareness in the event an emergency occurs while in containment. [*GAPIII subelement 10.3.1 guidance*]

Note: The U.S. NAC will share event information with WHO PV Containment Team and CDC PV response personnel to ensure appropriate measures are being taken.

5.1. Emergency Scenarios

Poliovirus-essential facilities must identify and document all credible, foreseeable, and reasonable emergency scenarios that could impact their PV programs [*GAPIII subelement 10.1.1*] and develop written response procedures for each event type. [*GAPIII subelement 10.2.1*] To plan for potential emergencies, PEFs must consider at least the scenarios included in the guidance section of GAPIII subelement 10.1.1 (Appendix I). Site-specific risk assessments may rule out non-credible or

unreasonable scenarios within the list but may identify additional applicable scenarios. Poliovirus-essential facilities should document the rationale for adding or dismissing emergency scenarios. [*GAPIII subelement 10.1.1 guidance*] In addition, PEFs should conduct new or review existing risk assessments when developing or revising emergency response procedures. [*GAPIII subelement 2.2.1 guidance*] Please see the U.S. NAC *Biorisk Management and Risk Assessment* policy for information and guidance on performing risk assessments.

5.2. Emergency Management Plans and Procedures

Poliovirus-essential facilities must establish and maintain emergency response plans and procedures to "1. identify the potential for incidents and emergency scenarios involving biological agents, toxins and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them." [*GAPIII subelement 10.2.1*] In consultation and coordination with external partners (*e.g.,* local emergency responders such as police and security services, fire, ambulance and hospital care; environmental authorities; couriers; local/state health departments; WHO, etc.), PEF emergency response plans must include written procedures to manage confirmed PV infections [*GAPIII subelement 10.2.2*] and incidents that result in PV exposure(s) or compromises the security of the PV containment area(s) (see Appendix II for plan requirements). [*GAPIII subelement 10.3.1*]. State and local health departments should have procedures in place to address issues of non-compliance (*e.g.,* exposed individuals refusing to quarantine). Additional information on work-related PV infections and exposures are provided in Appendices III and IV of this document, as well as the Post-Exposure Procedure section below.

Poliovirus-essential facilities must assess their plans to ensure "legality and enforceability of proposed emergency response plans". [*GAPIII subelement 10.3.1 guidance*] Poliovirus containment emergency response procedures may refer to elements outlined in their internal, institution-level emergency response plans.

Poliovirus-essential facilities must identify an institutional individual to serve as an emergency manager/coordinator that ensures the PEF PV response plans and procedures incorporate and align with all requirements and recommendations outlined in GAPIII, U.S. NAC policies, and WHO Public Health Management of Facility Related Exposure to Live Polioviruses. This person should report to top management and be involved in all emergency plan and procedure development, PV evaluation/response team planning and action (see below), as well as PEF emergency response exercises and simulations (see below). [*GAPIII subelement 10.4.1*]

Poliovirus-essential facilities must apply all emergency response assessment and analysis processes to "near-misses" as these events provide PEFs with the opportunity to improve mitigations to prevent a similar event from becoming an exposure or incident in the future. These processes must include ongoing data collection and analysis of all PEF incidents, infections, exposures, and "near-misses" to identify trends (*e.g.,* frequency, type, severity, etc.) and enhance mitigations and improve the safety of all individuals entering PV containment area(s). [*GAPIII subelement 11.1.1 guidance*]

5.3. Medical Emergencies

Poliovirus-essential facility must establish a system "to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers." [*GAPIII* sub*element 9.3.1*]

The PEF medical emergency system must include procedures for first aid, determinations for medical personnel entering containment area(s) including PPE and immunizations, and work performed during business hours and after hours. Procedures must ensure that the risk of contamination to the environment and responders is mitigated. Medical emergency procedures must "ensure that adequate emergency planning is provided to address worker health needs in the event of an accident or emergency situation" and include "first responders and their families, to members of the broader community and to environmental conditions that may have been affected by the incident." [*GAPIII guidance 9.3.1*]

Poliovirus-essential facility medical emergency procedures must address potential credible emergency scenarios (*e.g.,* infected worker/family member), support (*e.g.*, emergency services/local authorities' liaison), and equipment and other resources to manage a medical emergency (*e.g.*, hospitalization, isolation requirements, vaccines). Poliovirus-essential facilities should perform risk assessments to ensure adequate first aid is available for emergency scenarios. Poliovirus-essential facility procedures should also ensure trained personnel are available on-site and include additional medical support (*e.g.,* hospitals, isolation units). [*GAPIII guidance 9.3.1*] Poliovirus-essential facility medical emergency plans, materials, and supplies should be maintained and periodically tested to identify gaps (*e.g.,* annually). [*GAPIII guidance 9.3.1*].

5.4. Poliovirus Evaluation/Response Team

Poliovirus-essential facilities must assemble a PV evaluation/response team to analyze "near-misses" and incidents to determine PV exposures. [*GAPIII subelement 10.3.1, 11.1.1 guidance*] Team members must include "facility medical, public-health and polio-specific expertise" personnel and others with decision-making authority such as facility Occupational and Environmental Health Directors, emergency manager/coordinator, Biosafety Officer, and PI. The team should report findings and recommendations to the senior manager and provide consultation, as necessary. [*GAPIII subelement 11.1.1 guidance*] The roles and responsibilities of each team member should be clearly defined and report to the appropriate authority (e.g., senior manager, top management). [ii] Poliovirus-essential facilities must include PV evaluation/response team members in 1) emergency response plan and procedure development and 2) exercises and simulations that test the effectiveness of the facility plans.

5.5. Incident Investigations

Poliovirus-essential facilities must establish and maintain procedures to document and analyze "near-misses" and incidents in PV containment area(s) and provide the appropriate care to individuals. [*GAPIII guidance 9.1.2, 9.3.1, 11.1.1*] Procedures to determine infection must include consultation with a medical professional familiar with PV infections and symptomology and, in the event of an exposure, include vaccination, PPE, testing, and potential isolation. [*GAPIII subelement 9.1.2 guidance*] Poliovirus-essential facilities should coordinate incident investigations with local and state health departments that will conduct contact tracing to identify all potentially exposed individuals. [iv] Please see Appendices III and IV for additional guidance on managing exposures and infections as well as the U.S. NAC *Policy for Personal Protective Equipment and Hand Hygiene Practices* for information on PPE.

Poliovirus-essential facilities must clearly define the criteria to determine incidents, infections, exposures, and "near-misses", which must be applied to all PV-related incident and exposure procedures. In addition, these procedures must be communicated with all relevant PEF and external partner personnel. [*GAPIII subelement 11.1.1 guidance*] Poliovirus-essential facility communication

and coordination with local and state agencies is critical at the onset and throughout an incident to ensure an effective response. Incident investigation procedures must be coordinated with the PV evaluation team and all relevant PEF and external partner personnel. In addition to establishing a PV evaluation/response team, PEFs incident investigation procedures must include the following definitions, processes, etc. outlined in the guidance of GAPIII 11.1.1:

- Definitions and criteria for incidents, infections, exposures, and "near-misses", including what "triggers recording and reporting". [ii] Emphasis should be placed on events, including "near-misses" of the same, resulting in significant exposures such as sticks, splashes, spills, leaks, aerosols, or other breaches of containment.
- Establishing and communicating 24-hour incident reporting channels, including personnel responsible for management and maintenance.
- Processes for PV evaluation/response team to determine infections, exposures, and near-misses and report recommendations to senior management.
- Personnel responsible for maintaining the incident reporting channels and system.
- Documentation required to support the system (*e.g.,* records of incident investigations, communications, reports).
- Frequency of communicating reports to relevant personnel.
- Ongoing analysis of exposure, incident, injury, and "near-miss" data to identify trends including:
    - Types and frequencies of each event
    - Responses to each event
    - Changes to procedures following each event
    - Incident occurrence following procedural changes designed to mitigate future events.
- Processes to identify incident root causes.
- Identify situations that may require security professionals to coordinate with law enforcement (*e.g.,* theft of material).

5.6. Managing PV Exposures

The PEF PV evaluation/response team must assess each potential incident or exposure to determine 1) if an exposure has occurred, 2) what is the risk level, and 3) if the event needs to be reported to CDC, local and state health agencies (*e.g.,* "near-misses" would not be reported to CDC). If the PV evaluation/response team determines that an incident-associated exposure has occurred, PEFs must also identify the risks associated with the PV exposure event. The WHO Public Health Management of Facility Related Exposure to Live Polioviruses provides guidance on event risk stratification, which the U.S. NAC has updated below to include WPV/VDPV of all three serotypes. Unless specified, the incidents listed in the table pertain to IM of each PV material type. Guidance on managing PV-exposed and infected individuals, and their contacts for each risk level are provided in Appendices III and IV, respectively. Note: The U.S. NAC has removed Minimal Risk from the following table as GAP III containment does not currently apply to SL1, SL3, and SL2 PIM at U.S. facilities.

Risk	Incidents corresponding to risk level
Very high risk	• "Any containment breach or exposure involving" [iv] of any WPV/VDPV IM serotype
High risk	• "Any exposure involving Sabin-Like PV type 2 (SL2) "in a country or surrounding area (within a radius of 100 km) with inadequate type 2 immunity (<90% IPV coverage according to the respective national schedule[6]) OR has lower access to basic or safely managed sanitation (< 95% of the population as per UNICEF / WHO JMP data)" [iv]
Low risk	• "Any exposure involving SL2 in a country and the surrounding area with adequate type 2 immunity (>90% IPV coverage) AND higher access to basic or safely managed sanitation (converse of high risk as above)." [iv] • "Any exposure involving WPV2 / VDPV2 PIM" [iv] or WPV3/VDPV3 PIM

5.6.1. Reporting of exposures and incidents

The PEF designated Point of Contact or Institutional Representative must immediately telephone the CDC Emergency Operations Center (EOC) (770-488-7100) as well as local and state authorities to report any PV exposures and incidents, regardless of the risk level. The CDC EOC will notify the U.S. NAC and other CDC response teams following the PEF notification. Within 12 hours of the incident, PEFs must email the completed sections A and B of the U.S. NAC Facility Incident Reporting Form to the U.S. NAC at poliocontainment@cdc.gov. Within 72 hours, the PEF PV evaluation/response team must complete 1) section C of the U.S. NAC Facility Incident Reporting Form and 2) a risk assessment as outlined in the WHO Public Health Management of Facility Related Exposure to Live Polioviruses. Please contact the U.S. NAC for questions. The U.S. NAC will send an email to the PEF to confirm receipt of all U.S. NAC Facility Incident Reporting Form submissions.

Poliovirus-essential facilities must maintain records associated with PV exposures, incidents, and "near-misses" that occur at the facility. Records must be maintained by the PEF for a minimum of 10 years after withdrawal from the containment certification process or scheme. [*GAPIII subelement 1.4.2*] Poliovirus-essential facilities should consider coordinating with local and state health agencies, as well as CDC, to prepare for media inquiries in advance of such an event.

5.7. Post-Exposure Procedures

Poliovirus-essential facilities must develop written procedures regarding individuals who are exposed to PV material. [*GAPIII subelement 10.3.1*] Procedures should provide detailed information including, but not limited to: appropriate first aid to individual (*e.g.,* eye wash, wound site); PPE requirements; waste disposal; and notifications of first responders and local, state, and federal agencies, including CDC. [*GAPIII guidance 9.3.1*]

Exposed individuals must monitor their health status (*e.g.,* temperature, symptoms) and report to the PEF occupational health professional as well as local and state health agencies managing the exposed individual. Baseline temperature and symptoms should be established immediately after the exposure to assess progression of infection. The exposed individual must have daily phone calls with state health agencies and immediately report changes in temperature (*i.e.,* >100°F) or

[6] National level per WUNEIC estimates at time of publication.

development of flu-like (*e.g.,* fever, fatigue, headaches, vomiting), or neurological (*e.g.,* neck stiffness; pain in arms and legs; weakness; paralysis; difficulty breathing, swallowing or speaking) symptoms to the PEF occupational health professional, who will report to the local and state agency monitoring individuals.

5.7.1. Specimen Collection and Testing

The CDC outbreak response teams coordinate post-exposure procedures, including testing, specimen and waste collection and disposal, and home isolation, with local and state agencies that will be involved in managing individuals exposed to and/or infected with PV. Post exposure procedures must include "collecting and testing nose, throat and stool specimens daily for a minimum of seven days post-exposure", including the day of the exposure. [*GAPIII subelement 10.3.1*] Poliovirus-essential facilities should consider 1) collecting and testing serum samples 15-21 days after exposure to determine antibody levels and 2) establishing appropriate sample storage conditions (*e.g.,* -20°C freezer) in the event samples require additional testing (See U.S. NAC *Policy for Occupational Health Programs at Poliovirus-Essential Facilities* to establish baseline immunity levels*)*. Sample collection and testing must begin immediately once a potential exposure has been determined as individuals are often asymptomatic. If stool testing reports are positive for PV, testing should continue daily until 3 consecutive negative stool samples have been reported. If stool samples are negative, home isolation and monitoring should discontinue after 7 days. [iv] Droplet precautions must be implemented if throat samples are positive. [iv]

The CDC response teams will work with local and state health departments to 1) ensure stool, throat, and nasal sample collection kits are provided to individuals being monitored and 2) determine how samples will be collected within the home, 3) how the samples will be transported to a laboratory for testing, and 4) who will collect the samples from the individual to identify and prevent additional exposures or risk to the community. CDC will perform diagnostic testing of post-exposure samples and the local and state health departments must coordinate transfer agreements and shipments to ensure the safe transport of samples. Poliovirus-essential facilities that have NAC approval and capacity to perform in-house serological testing may do so according to facility procedures. Please see the U.S. NAC *Policy for U.S. Facilities to Transfer Poliovirus Materials* for information on shipping PV materials.

5.7.2. Home Isolation

Poliovirus-essential facilities should coordinate home isolation procedures with appropriate federal, state, and local agencies, for all individual(s) exposed or infected at the PEF, including immunized persons. Exposed individuals should be in isolation for a minimum of 7 days while infected individuals should remain in isolation "until the individual is free of poliovirus in stools for three consecutive days". [*GAPIII subelements 10.2.2 and 10.3.1, guidance 9.3.1*] Poliovirus-essential facilities should develop and coordinate criteria and procedures for hospital isolations with local and state health departments, in the event an infection requires hospitalization. (See Appendices III and IV for guidance). Coordination with local and state health agencies is critical to ensure compliance with isolation procedures. Failure to comply with active monitoring activities and home isolation could jeopardize the health of the individual(s), expose household members and close contacts, or release PV into the environment and potentially expose the general public.

Home isolation procedures must consider providing exposed individual(s) with materials (*e.g.,*

surgical masks and specimen collection kits, gloves, disinfectants) needed to maintain infection control standards, including materials for household members and close contacts, if necessary. Local and state health departments must arrange to collect and disinfect human waste (*e.g.,* stool, respiratory secretions) from PV-infected individuals and ensure the waste is disposed according to local and state regulations. [*GAPIII subelement 10.2.2*]

Poliovirus-essential facility home isolation procedures must also include educating individuals being monitored, families, and close and frequent contacts on 1) isolation and quarantine procedures, 2) risks of PV to the community, and 3) procedures for diagnosis and the precautionary measures required to prevent possible transmission. In addition, PEFs must notify and communicate with appropriate local, state, and national agencies to determine if a community vaccination plan needs to be enacted; and disinfecting areas potentially contaminated by infected individuals. The U.S. NAC will communicate with WHO on behalf of the PEF. [*GAPIII subelement 10.2.2*]

Individuals isolating at home should consider the following infection control measures to prevent an individual from contaminating other persons and the environment.

- Toileting
  - Wash hands before and after toileting.
  - Use a separate restroom.
  - Avoid or limit close contact with other persons.
  - Flush with toilet lid closed
  - Use medical gloves while using the toilet, sampling and disposing of feces
- Wash hands and/or don gloves before and after food preparation and meals
- Disinfect sinks and showers after use with sodium hypochlorite (*i.e.*, bleach)
- Use separate toiletries (*i.e.,* isolated individuals should not share toiletries such as toothbrush, towels, washcloth). Wash clothing separately from other persons
- Use disposable cups, plates and utensils
- Separate solid waste generated by infected individuals. Consult with local and state health departments for proper disposal
- Wear a surgical mask when in the presence of others

5.8. Exercises and Simulations

Poliovirus-essential facilities must perform exercises or simulations (hereinto referred as exercises) at least annually to test PEF emergency response plan and procedures. [*GAPIII subelement 10.4.1*] Poliovirus-essential facilities should exercise emergency scenarios that include laboratory safety, security, and emergency response procedures annually. The exercises should include all relevant PEF and external partner personnel to ensure adequate preparation for a real-world event. Exercises are not required in calendar years in which emergency response plans or procedures are activated for a real-life event. Poliovirus-essential facilities should resume exercises the calendar year following a real-life event.

Exercises provide PEFs with an opportunity to train essential, medical, and external partner personnel who may be involved in a PV-related emergency response. Training could include roles and responsibilities of personnel in response procedures, PPE requirements and donning/doffing procedures, and notification and reporting procedures in various emergency scenarios. [*GAPIII subelement 9.3.1 guidance*] If an exercise is used to train personnel, the PEF must document the

date, scenario, procedures tested, and personnel involved in the exercise.

Exercises must be documented, including date, attendees, description of the exercise including how the plan was tested and evaluated, after action goals and objectives, and changes made to emergency response plans and procedures following the exercise. In addition, PEFs must establish processes (*i.e.,* delegate personnel to manage implementation, timelines, reporting to top management) to ensure that after action goals and objectives are addressed and implemented. Poliovirus-essential facilities must communicate changes to emergency response plans and procedures to PEF personnel and external partners, provide training for personnel on the changes. Please contact the U.S. NAC (poliocontainment@cdc.gov) for additional information and guidance.

5.9. Appendix I: Emergency Scenarios

Excerpted from GAPIII subelement 10.1.1 and guidance.

"To plan for emergencies, all credible emergency scenarios must be considered. It is unlikely that all potential scenarios will be credible, but all reasonable threats should be considered and recorded and, where appropriate, the rationale for dismissing any issue should be provided.

Scenarios considered should include:

a. an infected/potentially infected worker or other contact (*e.g*., family member, emergency responder or community member);
b. accident or illness to a worker within the containment area and need for evacuation;
c. fire;
d. flood;
e. breach of security;
f. explosion;
g. the potential loss of poliovirus through theft or any other reason;
h. unexpected virulence (unknown biological agents or biological agents expected to be avirulent);
i. physical facility and equipment failure, including a control system failure of the disinfection regime;
j. utility failure including electricity, gas, steam and water supplies;
k. a major spillage/aerosol release;
l. environmental release;
m. a natural disaster (*e.g*., earthquake, extreme weather conditions, disease pandemics);
n. an act of terrorism or deliberate vandalism, extortion;
o. intense media attention."

5.10. Appendix II: Incident Response Plan Requirements

Plan requirement	Procedures	Reference
Written procedures	Procedures are established and maintained to: 1. identify the potential for incidents and emergency situations involving biological agents, toxins and materials; 2. prevent their occurrence; 3. respond to emergency situations; 4. limit the likelihood of illness or other damage that may be associated with them.	*GAPIII subelement 10.2.1*

Plan requirement	Procedures	Reference
Description of Roles for individuals participating in incident responses and exercises	Identify and define roles, responsibilities, contact information, and lines of communication for: • PV evaluation/response team • PEF staff • External partners (*e.g.,* local emergency responders such as police, fire, ambulance and hospital care; environmental authorities; security services; transport couriers; local/state health departments; WHO, etc.) • Other applicable staff involved in developing, implementing, testing, and communicating incident response procedures	*GAPIII subelement 10.3.1* *GAPIII subelement 10.3.3 guidance*
Response procedures	Refer to Appendix I for emergency scenarios to be included in the plan	*GAPIII subelement 10.1.1* *GAPIII subelement 10.1.1 guidance*
Additional plan provisions	• After hours procedures for incidents that occur outside normal operating hours when staff is reduced including holidays and weekends. • Access and exit procedures, including evacuation (*e.g.,* evacuation types, exit route assignments, safe distances, places of refuge). • Mechanisms to override access in the event of a power outage or access required by emergency responders. • Safe removal, transport, transfer, treatment (*e.g.,* first aid) and accommodations for contaminated persons and objects from PV containment area(s) affected by an incident. • Requirements for procuring, donning, and doffing PPE required to enter PV containment area(s) or treat PV-exposed individuals. • Incidents requiring coordination with law enforcement.	*GAPIII subelement 10.3.1 guidance* *GAPIII subelement 11.1.1 guidance*
Contingency planning	Procedures for use of alternative storage conditions, facilities, personnel, or backup systems including redundancy or replacement.	*GAPIII subelement 10.5.1* *GAPIII subelement 10.5.1 guidance*

Plan requirement	Procedures	Reference
Post Exposure	• Procedures to investigate and assess a potential exposure and, if the individual(s) were exposed to PV, determine if the individual(s) were infected • Definitions for incidents, near-misses, exposures, infections, etc. • Specimen collection & testing procedures • Home isolation procedures for exposed individuals (See Appendix III for guidance) • Procedures for managing confirmed infections • Disinfection procedures for areas potentially contaminated by infected individuals. • Communication and reporting procedures with relevant local, state, national officials	*GAPIII subelement 10.2.2* *GAPIII subelement 10.3.1*
Notification and Reporting	Procedures for incident reporting (see Incident Reporting section of policy)	*GAPIII subelement 11.1.1*
Training	Training on emergency and incident response procedures should be described (e.g., applicability, requirements, frequency) and must include: • PEF personnel • External partner personnel • Exposed individuals under evaluation, household members, family, and close contacts • Visitors and non-essential personnel	*GAPIII subelement 9.3.1 guidance* *GAPIII subelement 10.2.2* *GAPIII subelement 10.3.1* *GAPIII subelement 10.3.3* *GAPIII subelement 10.3.3 guidance*

5.11. Appendix III: Management of PV-exposed persons and their contacts

Excerpted from Section 9 of WHO Public Health Management of Facility Related Exposure to Live Polioviruses. [iv]

Activity	Low risk event	Very high risk or high risk event
Exposed person		
Isolation - location	At home	If possible and supported by national/local legal framework, hospital isolation room withsingle bathroom if available should be considered for very high-risk events, particularly if compliance with other control measures is likely to be low. Otherwise home isolation may be used. Publichealth workers should frequently monitor compliance to ensure strict isolation from household contacts including separate toileting and bathroom, stringent cleaning, disinfection and waste disposal. Stools must be collected and incinerated.
Isolation - duration	Seven days if testing is negative	
Specimen collectionand transport to a	Daily collection of stool specimens and throat swabs for the presence of poliovirus for at least seven days Baseline blood sample on day of exposure and 15 – 21 days later, as per	

Activity	Low risk event	Very high risk or high risk event
GPLN accredited laboratory	GPLN guidance (see section 4.1)	
Management of faeces	General sewerage	*Very high risk:* Collected and incinerated orotherwise inactivated, see also section 10 *High risk:* Collected and incinerated orotherwise inactivated if the toilet not connected to adequate wastewater management
Health care workers	Hand washing, good hygiene	Appropriate barrier practices: enteric precautions using gown and gloves Respiratory precautions may be required ifthe person is unvaccinated, until throat specimens are shown to be negative.
Cleaning, disinfection	Household bleach or appropriate equivalent –see section 11	Enhanced cleaning and disinfection – seesection 11
Waste disposal, including laboratory samples	Encourage good practices	Should be managed as infectious waste.
Food handling (for other people)	Not permitted	Not permitted
Childcare (non-household)	Not permitted	Not permitted
Visitors	Should be limited to close family / friends /care providers with proven PV immunity or vaccination history may visit but must take enteric precautions. If throat swabs are positive, droplet precautions also required.	

5.12. Appendix IV: Management of PV-infected persons and their contacts

Excerpted from Section 9 of WHO Public Health Management of Facility Related Exposure to Live Polioviruses. [iv]

Activity	SL2	WPV, VDPV
Case management		
Isolation - location	Home isolation with frequent monitoring to ensure compliance of the SL2-infected person and household contacts with control measures is high. Public health workers should check compliance with strict isolation from household contacts including separate toileting and bathroom, stringent cleaning, disinfection, and waste disposal. Stools should be collected and incinerated or otherwise inactivated.	Hospital isolation room with single bathroom with appropriate waste management

Activity	SL2	WPV, VDPV
Duration of isolation	Until three negative stool samples collected on three consecutive days	
Health care contacts	Appropriate barrier practices: enteric precautions using gown and gloves. PPE should be properly disposed after use. In cases of proven WPV / VDPVinfection who are symptomatic, or whose throat swabs are positive, droplet precautions should also be employed.	
Management of faeces	Collected and incinerated or otherwise inactivated; see also section 10	
Cleaning and disinfection	Enhanced cleaning and disinfection – see section 11	
Waste disposal	Waste should be treated as infectious	
Food handling (for other people)	Not permitted	
Childcare (non-household)	Not permitted	
Visitors	Should be limited, and if allowed, restricted to close family / friends / care providers only, and only those with proven PV immunity or vaccination history may visit, but must take enteric precautions. If throat swabs are positive, droplet precautions also required.	
Contacts of the PV infected person		
Household contacts	Quarantine at home. Take two further stool samples at least three days after the contact's most recent exposure 24 to 48 hours apart. Contacts can be released from quarantine when two stool samples taken 24 to 48 hours apart are shown to be negative for poliovirus.	• Quarantine at home, if not already implemented. • Take two further stool samples at least three days after the contact's most recent exposure 24 to 48 hours apart. • Contacts can be released from quarantine when two stool samples taken 24 to 48 hours apart are shown to be negative for poliovirus.
Toilet contacts Food consumer contacts	• Quarantine at home. • Take two further stool samples at least three days after the contact's most recent exposure 24 to 48 hours apart. • Contacts can be released from quarantine when two stool samples taken 24 to 48 hours apart are shown to be negative for poliovirus.	• Quarantine at home, if not already implemented. • Take two further stool samples at least three days after the contact's most recent exposure 24 to 48 hours apart. • Contacts can be released from quarantine when two stool samples taken 24 to 48 hours apart are shown to be negative for poliovirus.
Exposed sewage workers	• No quarantine. • Take two stool samples at least three days after the contact's most recent exposure 24 to 48 hours apart. Can be considered negative when two stool samples taken 24 to 48 hours apart are shown to be negative for poliovirus.	

Activity	SL2	WPV, VDPV
Vaccination – all at-risk contacts	Take and test a baseline serum sample prior to vaccination with a booster dose of IPV, or if vaccination status is unknown, offer a full course of IPV. Vaccination should not be delayed whilst waiting for a result to the antibody test.	
Vaccination – community	Encourage community assessment and enhancement of routine immunization schedule (*e.g.*, IPV)	

6. References

6.1. Internal References

Reference
U.S. NAC *Biorisk management and risk assessment* policy
U.S. NAC *Policy for Poliovirus Occupational Health Programs at U.S. Poliovirus-Essential Facilities*
U.S. NAC Facility Incident Reporting Form
U.S. NAC *Policy for Personal Protective Equipment and Hand Hygiene Practices*
U.S. NAC *Policy for U.S. Facilities to Transfer Poliovirus Materials*

6.2. External References

#	Reference
i.	WHO Containment Certification Scheme
ii.	World Health Organization. Global Action Plan III. 2015
iii.	Van Damme, P., et al., The safety and immunogenicity of two novel live attenuated monovalent (serotype 2) oral poliovirus vaccines in healthy adults: a double-blind, single-centre phase 1 study. Lancet, 2019. 394(10193): p. 148-158.
iv.	World Health Organization. Public Health Management of Facility Related Exposure to Live Polioviruses. February 7, 2019
v.	Occupational Health and Safety Administration. Near-Miss Incident Report Form
vi.	WHO Containment Activity Group, Report of the Second Meeting of the Containment Advisory Group, November 2017
vii.	World Health Organization. Laboratory Safety Manual 4th Edition. 2020
viii.	World Health Organization. Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses. 2018
ix.	World Health Organization. Poliomyelitis. 2018

7. Attachments

None

8. Acknowledgements

None

9. Version History

Version	Change Summary	Effective Date
01	New Document- Document group number has been changed, consequently leading to an update in the document number that was previously known as NAC.SHARED.POL.003.02.	02/29/2024