Policy for U.S. Facilities to Store Poliovirus Materials Outside of WHO GAPIII Containment

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NAC
U.S. NATIONAL AUTHORITY
FOR CONTAINMENT OF POLIOVIRUS

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE
CONTROL AND PREVENTION

Office of Readiness and Response

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Contents

1. Purpose

It is the policy of the U.S. National Authority for Containment (NAC) of Poliovirus located at the Centers for Disease Control and Prevention (CDC) that Poliovirus-Essential Faculties (PEFs) may store poliovirus (PV) infectious and potentially infectious materials (IM and PIM, respectively) outside of the laboratory containment perimeter stipulated by World Health Organization Global Action Plan, 3rd edition (GAPIII). This policy applies to PV IM and PIM (PV materials) of all three serotypes.

In 2017, GAPIII was amended to allow storage of PV materials outside of GAPIII containment [*GAPIII guidance 3.1.1*] and U.S. NAC to establish requirements for PEFs storing PV materials outside of laboratories meeting GAPIII containment. Because PV materials pose a risk to personnel, the environment, and the global eradication of PV, the U.S. NAC requires PEFs to implement risk mitigation strategies as stated in this policy to ensure the safe and secure storage of PV materials outside of laboratories meeting GAPIII containment. Poliovirus essential facilities must also conduct a site-specific risk assessment for these storage locations and may adopt additional hazard control measures.

Please note that this U.S. NAC Storage Outside of Containment policy (NAC.AUDIT.POL.006.XX) supersedes the previously published U.S. NAC Storage Outside of Containment policy (NAC.AUDIT.POL.006).

2. Scope

The following statements apply to this policy:

- **Only U.S. facilities that possess or are in pursuit of a Certificate of Participation [i] (CP) issued by the U.S. NAC may be in possession of or receive wild PV/vaccine-derived PV (WPV/VDPV) type 1 IM.** U.S. facilities with OPV potentially infectious materials (PIM) should consider the WHO PIM Guidance document while U.S. facilities with WPV/VDPV 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 oral polio vaccine (OPV) type 2 IM must implement GAPIII and apply for an Interim Certificate of Containment (ICC).** [i]
- 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 epidemiological situation, vaccination coverage, new international policies, or changes in 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
GAPIII	WHO Global Action Plan, Third edition
IM	Infectious materials
NAC	National Authority for Containment of Poliovirus
OPV/Sabin	Oral poliovirus vaccine
PEF	Poliovirus essential facility
PIM	Potentially infectious materials
PRP	Personnel reliability policy
PV	Polioviruses
VDPV	Vaccine-derived poliovirus
WHO	World Health Organization
WPV	Wild poliovirus

4. Definitions

Term	Definition
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.

Term	Definition
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; • 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]

[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.
[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
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
Personal Protective Equipment	"Equipment and/or clothing worn by personnel to provide a barrier against 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." [iii]
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 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.
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." [iv]

Term	Definition
Poliovirus materials	Unless a serotype is specifically identified, PV materials refer to IM and PIM of all three PV serotypes.
Vaccine derived poliovirus	Classified with wild polioviruses and usually demonstrate 1–15% sequence 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. Storage Outside of Containment

The WHO GAPIII establishes international standards for primary safeguards of facility containment to reduce the risk of facility-associated poliovirus release. In 2017, GAPIII was amended to allow storage of PV materials outside of GAPIII containment [*GAPIII guidance 3.1.1*] and U.S. NAC to establish requirements for PEFs storing PV materials outside of laboratories meeting GAPIII containment. U.S. NAC requires that PEFs adopt risk mitigation strategies to minimize risk of an unintentional release or loss of these materials. Poliovirus essential facilities must also conduct a site-specific risk assessment for these storage locations and may adopt additional control measures.

5.1 Facilities Retaining WPV/VDPV/OPV2 Infectious Materials and WPV/VDPV Potentially Infectious Materials

Section 5.1 applies to PEFs retaining WPV/VDPV IM of all three serotypes and OPV2 IM, as well as U.S. facilities retaining possess WPV/VDPV PIM of all three serotypes.

Required risk mitigation strategies are outlined in Appendix 1. Strategies described below are not required for materials lacking a checkmark in Appendix 1. Risk mitigation strategies are required for storage of PV materials outside of the WHO GAPIII containment laboratory perimeter. PEFs must implement security and biosafety strategies to safeguard PV materials which include, but are not limited to, the following conditions.

Note, where GAPIII elements are indicated, these strategies are also required for poliovirus material storage in the GAPIII containment laboratory. Further, records created to comply with GAPIII "are maintained in paper or electronic form for a minimum of 10 years." [*GAPIII subelement 1.4*]

5.1.1 Security Strategies

5.1.1.1 Limited Access to Storage Areas

Access must be limited to authorized personnel in accordance with institutional policies and meeting the requirements outlined in this policy statement *(Refer to U.S. NAC Security Policy).*

5.1.1.2 Locked Storage Unit

Storage units containing PV materials must be locked to prevent unauthorized access. Appropriate locks include a padlock, combination lock or other unique means to restrict access rather than use of a standard manufacturer installed lock. [*GAPIII subelement 16.1.1*]

5.1.1.3 Storage unit dedicated for poliovirus materials

Infectious PV materials are stored in dedicated units (*e.g.,* ensuring samples of wild and OPV/Sabin poliovirus materials are segregated from each other and other virus isolates, cell lines, cultures or other materials that could be subject to cross-contamination or misidentification). *[GAPIII guidance 3.1.1]*

It is recommended that PV materials are clearly labeled and segregated (*e.g.,* separate freezer rack) from other PV and non-PV materials.

5.1.1.4 Segregate poliovirus materials in shared storage unit

Potentially infectious materials (PIM) are labeled and segregated from other materials (*e.g.,* separate box, rack or shelf) within a shared storage unit. *[GAPIII guidance 3.1.1]*

5.1.1.5 Authorized trained personnel

Access to storage units containing PV materials is limited to trained and authorized personnel. [GAPIII element 5]

5.1.1.6 Personnel Reliability Program (PRP) for authorized personnel

Personnel authorized to access storage units containing infectious PV materials comply with the facility's PRP. *[GAPIII subelements 16.3.1, 16.3.2] (Refer to U.S. NAC Security Policy)*

5.1.1.7 Record of access to storage unit

A record of access must be kept for each time the storage unit containing PV materials is opened, in accordance with recordkeeping requirements implemented for the GAPIII containment perimeter (*Refer to U.S. NAC Security Policy)*. *[GAPIII guidance 16.1.1]*

5.1.1.8 Inventory

Poliovirus essential facilities must maintain a current, qualitative inventory of PV materials in their possession *(Refer to U.S. NAC Inventory Policy)*. *[GAPIII subelements 3.1.1, 3.2.1]*

5.1.1.9 Transfer Protocols

Facility must establish protocols for safe and secure transfers of PV materials between laboratories at the facility or to and from the facility. U.S. NAC must be notified of PV material transfers to other PEFs to ensure the U.S. inventory of poliovirus materials is current. *(Refer to U.S. NAC Transfer Policy) [GAPIII subelement 3.3.1]*

5.1.2 **Biosafety Strategies**

Note, PEFs have flexibility on risk mitigation strategies that are used to ensure the continued safe storage and handling of PV material containers.

5.1.2.1 Impact resistant containers

Storage of infectious PV materials that are to remain in a viable or intact state must be held in at least one impact-resistant container (*e.g.,* plastic screw top cryovial). If

the primary container is not impact- resistant, the material may be enclosed in a secondary container that is impact resistant rather than transferring the material into a new primary container (*e.g.,* glass vial located within plastic conical tube, specimen tubes located in gasketed transport container).

Note, packaging of material must occur in WHO GAPIII containment laboratory and a primary containment device (e.g., biosafety cabinet) if the primary container is changed or primary container integrity is unknown or breakable (*e.g.,* glass ampules). [*GAPIII subelement 12.3.1.e]*

5.1.2.2 Leak-Proof containers

Storage of PV IM that are to remain in a viable or intact state must be held in at least one leak proof container. If the primary container is not leak proof, the material may be enclosed in a secondary container that is leak proof rather than transferring the material into a new primary container (*e.g.,* sealed plastic bag, protective wrapping, gasketed transport container).

5.1.2.3 Opening primary container occurs in GAPIII containment laboratory

Opening the primary container of PV material that is in a viable or intact state is permitted only in a WHO GAPIII containment laboratory. Appropriate controls must be in place to ensure that primary containers of PV materials are not manipulated outside of the GAPIII containment laboratory and primary containment devices. *[GAPIII subelement 12.3.1.e]*

Facilities that discover a leak in PV packaging must immediately move the package to a BSC within the GAPIII containment laboratory. The facility must decontaminate all associated surfaces and that came in contact with the package or may harbor leaked material. Facility handling of leaking packages and containers, including decontamination of surfaces contaminated by the package, must be included in the facility breach of containment procedures.

5.1.2.4 Surface decontamination of containers

Poliovirus materials must be transferred through a disinfectant "dunk tank, decontamination chamber or other validated mechanism to ensure the disinfection of the exterior surfaces of any packaging materials" when removed from the WHO GAPIII containment perimeter. *[GAPIII subelements 12.3.1.j, 14.2.1]*

Once removed, packaged viable PV material must not be opened outside of the GAPIII laboratory containment perimeter unless inactivated by a validated method.

5.1.2.5 Personnel enrolled in occupational health program

Individuals with access to the storage unit must be enrolled in an occupational health program that addresses potential exposure to poliovirus materials. Further, "a system is established to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers." *[GAPIII element 9]*

5.1.2.6 Polio immunization of personnel required

Individuals with access to the storage unit must provide proof of poliovirus immunization according to the U.S. national immunization schedule. Documentation of antibody titers is acceptable in lieu of proof of immunization. If an individual cannot produce proof of polio immunization, the individual should be immunized according to national recommendations for persons with potential occupational exposure to poliovirus. *[GAPIII subelement 9.2.3]*

5.1.2.7 Proof of Immunity for personnel required

Individuals with access to the storage unit containing PV IM must provide evidence of immunity to all three serotypes (*i.e.,* serum neutralizing antibody titers greater or equal to 1:8). *[GAPIII guidance 9.2.3]*

Note, CDC will provide proof of immunity testing for personnel in U.S. PEFs. Contact U.S. NAC for information on how to request testing.

5.1.2.8 Transport procedures including chain of custody

Transport procedures must be developed and implemented. The biosafety plan or transport procedure must describe the method for safe transport of PV materials to and from the storage site within the facility, including the location of the storage area in relation to the WHO GAPIII containment laboratory. Transport procedures must take into account any safety requirements to protect personnel and the environment during transport. *[GAPIII subelement 15.1.1]*

Transport procedures for all PV material to and from the storage area should include a leak-proof secondary container, gloves and handwashing when handling all poliovirus material.

5.1.2.9 Emergency response procedures

Emergency response procedures for a release of stored PV material outside of the WHO GAPIII containment perimeter must be established. These must take into account measures to protect personnel and the environment in the event of a primary container breach, including a provision to follow the facility's exposure plan. Personnel must also report incidents, including "near misses" that "may trigger an investigation or emergency response", for stored PV materials in accordance with institutional policies. *(Refer to U.S. NAC Emergency Response Policy) [GAPIII elements 10, 11]*

5.2 Facilities Retaining OPV/Sabin Potentially Infectious Materials

5.2.1 Potentially Infectious Materials (OPV/Sabin and Related Strains)

Risk mitigation strategies are required for storage of PV PIM, as outlined in *Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses*. A site-specific risk assessment is also recommended for facilities retaining OPV/Sabin PIM.

5.2.2 Security Strategies

5.2.2.1 Locked storage unit

Storage units containing OPV/Sabin PIM must be locked to prevent unauthorized access. Further, OPV/Sabin PIM are clearly labeled and segregated (*e.g.,* separate freezer rack) from other stored material.

5.2.2.2 Authorized trained personnel

Access to storage units containing OPV/Sabin PIM is limited to specifically trained and authorized staff.

5.2.2.3 Inventory

Facilities must maintain current inventories of OPV/Sabin PIM in their possession.

5.2.2.4 Transfer protocols

Facilities must establish protocols for the transfer of OPV/Sabin PIM to other laboratories internal or external to the facility in accordance with institutional policies. U.S. NAC must be notified of material transfers to or from other facilities to ensure the U.S. inventory of facilities with PV materials is current.

5.2.3 Biosafety Strategies

For continued use of OPV/Sabin PIM, WHO recommendations are categorized by risk level of the material type (*e.g.*, fecal/sewage, respiratory) and activity (*e.g*., inoculated in poliovirus permissive cells, inoculated in non-poliovirus permissive cells). Additional information on biosafety containment conditions is available in the *Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses*.

6. References

6.1 Internal References

Reference
U.S. NAC *Policy for U.S. Poliovirus-essential facilities to control security of poliovirus materials and information* (Security Policy)
U.S. NAC *Policy for U.S. Facilities to Transfer Poliovirus Materials* (Transfer Policy)
U.S. NAC *Policy for U.S. Poliovirus-essential facilities to manage inventory* (Inventory Policy)
U.S. NAC *Policy For Emergency Response and Exposure Management Plans at U.S. Poliovirus-Essential Facilities* (Emergency Response Policy)

6.2 External References

#	Reference
i	WHO Containment Certification Scheme
ii	WHO Global Action Plan, 3rd Edition (GAPIII)
iii	World Health Organization. Laboratory Safety Manual 4th Edition. 2020
iv	World Health Organization. Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses. 2018

7. Appendix 1

Risk Mitigation Strategies for PV Material Storage Outside of WHO GAPIII Containment

RISK MITIGATION STRATEGY[1]	*TYPE OF PV MATERIAL*[2]		
	WPV, VDPV, or OPV IM	**WPV or VDPV PIM**	**OPV/Sabin PIM**
LIMIT ACCESS TO STORAGE AREA	✓	✓	
LOCKED STORAGE UNIT	✓	✓	✓
STORAGE UNIT DEDICATED FOR POLIOVIRUS MATERIALS	✓		
SEGREGATE POLIOVIRUS MATERIALS IN SHARED STORAGE UNIT		✓	
AUTHORIZED TRAINED PERSONNEL	✓	✓	✓
PRP FOR AUTHORIZED PERSONNEL	✓		
RECORD OF ACCESS TO STORAGE UNIT	✓		
INVENTORY	✓	✓	✓
TRANSFER PROTOCOLS	✓	✓	✓
IMPACT RESISTANT CONTAINERS	✓		
LEAK PROOF CONTAINERS	✓		
SURFACE DECONTAMINATION OF CONTAINERS	✓		
OPENING PRIMARY CONTAINER OCCURS IN GAPIII CONTAINMENT LABORATORY	✓	✓	
PERSONNEL ENROLLED IN OCCUPATIONAL HEALTH PROGRAM	✓	✓	
POLIO IMMUNIZATION OF PERSONNEL REQUIRED	✓	✓	
PROOF OF IMMUNITY FOR PERSONNEL REQUIRED	✓		
TRANSPORT PROCEDURES INCLUDING CHAIN OF CUSTODY	✓	✓	
EMERGENCY RESPONSE PROCEDURES	✓	✓	

8. Version History

Version	Change Summary	Effective Date
01	New document	12/6/2018
02	Document updated to include all PV, including WPV1, in addition to reformatting the policy to new NAC template.	02/29/2024

9. Acknowledgments

Prior to publication, U.S. NAC policies are developed in consultation with biosafety, biosecurity, legal, poliovirus, public health subject matter experts as well as poliovirus-essential facilities; endorsed by the CDC Officer of Readiness and Response, Board of Scientific Counselors; and reviewed by CDC technical experts and leaders. This U.S. NAC policy is a living document and subject to ongoing improvement. Please submit feedback or suggestions to poliocontainment@cdc.gov