Policy for Shared Use of Space Within U.S. Poliovirus-Essential Facilities

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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

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Contents

1. Purpose

This policy outlines the biosafety and security requirements for the shared use of PV containment area(s). The U.S. NAC recognizes that some U.S. facilities that possess or are in pursuit of a U.S. NAC-issued CP or ICC/CC [iii] may need to perform non-poliovirus (PV) work in PV containment area(s) used to work with and store PV IM declared eradicated by the World Health Organization (WHO)[1] and covered under Global Action Plan, Third Edition (GAP III)[2].

Please note that this U.S. NAC Shared Use policy (NAC.AUDIT.POL.015.03) supersedes the previously published U.S. NAC Shared Use policy (NAC.AUDIT.POL.015.02).

2. Scope

Only U.S. facilities that possess or are in pursuit of a Certificate of Participation (CP) or Interim Certificate of Containment (ICC)/Certificate of Containment (CC) issued by the U.S. National Authority for the Containment of Poliovirus (NAC) may be in possession of or receive wild poliovirus/vaccine-derived poliovirus (WPV/VDPV) infectious materials (IM) of all three serotypes or oral polio vaccine (OPV) type 2 IM. [i,ii]

The U.S. NAC recommends that facilities comply with WHO's GAP III element 12.3.1(c), stating "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." [iv] In support of this statement, WHO's Containment Advisory Group (CAG) recommends "the use of non-dedicated facilities (*e.g.,* Quality Control laboratories) may be permissible under a Certificate of Participation/Interim Certificate of Containment during Phase II of GAP III in association with the WHO CCS." [iii]

Note that GAP III element 12.3.1(c) requires poliovirus-essential facilities (PEFs) possessing PV at final eradication to dedicate containment area(s), permanently or temporarily, to PV work only and not permit concurrent non-PV work or storage within the space.

The U.S. NAC recognizes situations when PV *in vitro* and *in vivo* containment area(s) may need to be shared including, but not limited to, PIs sharing laboratory space due to limited laboratory space at the facility; PV Principal Investigators (PIs) having non-PV projects, but not enough laboratory space or equipment to effectively segregate PV work from non-PV work; and facilities that need higher containment laboratory space for surge capacity to perform non-PV work associated with outbreaks or emergencies. In addition to implementing the *in vitro* and *in vivo* mitigations outlined in the U.S. NAC Risk Mitigation Strategies (RMS), the U.S. NAC requires PEFs performing non-PV work in PV containment area(s) to implement the risk mitigations described below to prevent unintentional contamination or breach of containment. U.S. facilities remain responsible for the implementation of appropriate biosafety and security standards for non-PV agents in the containment perimeter (*e.g.,* BMBL).

The following statements apply to this policy:

- **Only U.S. facilities that possess or are in pursuit of a CP issued by the U.S. NAC may be in possession of or receive WPV/VDPV 1 IM.** U.S. facilities with oral polio vaccine (OPV) potentially infectious materials (PIM) should consider the WHO PIM Guidance document while U.S. facilities with WPV/VDPV

[1] WHO declared eradication of wild type 2 in September 2015; eradication of wild type 3 was declared in October 2019.

[2] Poliovirus IM covered under GAP III includes WPV/VDPV types 2 and 3, and OPV type 2.

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 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
BSC	Biosafety cabinet
CAG	Containment Advisory Group
CC	Certificate of Containment
CCS	Containment Certification Scheme
cDNA	Complimentary deoxyribonucleic acid
cVDPV	Circulating vaccine-derived poliovirus
CP	Certificate of Participation
GAPIII	WHO Global Action Plan, Third edition
HEPA	High-efficiency particulate air
ICC	Interim Certificate of Containment
IM	Infectious materials
IPV	Inactivated polio vaccine
NAC	National Authority for Containment of Poliovirus
OPV/Sabin	Oral polio vaccine
PBS	Phosphate-buffered saline
PEF	Poliovirus-essential facility
PI	Principal investigator
PIM	Potentially infectious materials
PPE	Personal protective equipment
PPM	Parts per million
PV	Polioviruses
RMS	*Risk mitigation strategies for in vitro and in vivo work with poliovirus infectious materials*
RNA	Ribonucleic acid
VDPV	Vaccine-derived poliovirus

Acronym	Definition
WHO	World Health Organization
WPV	Wild poliovirus

4. Definitions

Term	Definition
Circulating VDPV	VDPV isolates for which there is evidence of person-to-person transmission in the community.
Containment area	Laboratory area(s) listed on a U.S. PEF application that is used to work or store PV materials. A PV containment area may be a single room or a suite of rooms so long as access is limited to essential personnel.
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. IPV is a killed-virus vaccine and is administered by injection.

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 [3], 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 [4], 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 [5]." [i] 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 [6]; Cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains [7]." [i]
Oral polio vaccine /Sabin	"Attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains)." [i] 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

[3] For U.S. facilities, PV derivatives must contain a complete full-length WPV capsid sequence to meet the WPV IM definition.
[4] Expert panel will be determined by WHO.
[5] For U.S. facilities, PV strains must contain a complete full-length WPV capsid sequence to meet the WPV IM definition.
[6] For U.S. facilities, PV derivatives must contain a complete full-length OPV/Sabin capsid sequence to meet the OPV/Sabin IM definition.
[7] 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
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." [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 IM 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." [i] 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." [iii]
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. Shared Use of U.S. Poliovirus-Essential Facilities

5.1 Risk assessments

5.1.1 Poliovirus-essential facilities must perform risk assessments to identify risks associated with equipment and facilities shared for non-PV projects including, but not limited to, work and material (*e.g.,* PV-infected cell cultures, animals and animal tissues), storage (*e.g.,* freezers), equipment (e.g., centrifuges, incubators, biosafety cabinets (BSCs), microscopes, cage racks, animal restraint devices),decontamination (at minimum, all work surfaces and laboratory areas used), and waste disposal procedures (*e.g.,* disinfectants and contact time, solid and liquid waste disposal).

Poliovirus-essential facilities must demonstrate that the risk of breach of containment, cross-contamination, unauthorized access to materials and other factors have been fully documented, evaluated and addressed. [iv]

Based on risk assessment, PEFs must also establish *in vitro* and *in vivo* PV workflows to minimize cross-contamination (*e.g.,* perform lowest risk procedures first and perform the highest risk procedures last).

5.2 Handling PV and non-PV agents in shared space

5.2.1 Poliovirus-essential facilities must develop procedures to ensure that PV is the only agent handled in a shared space when active PV work is in progress. For a suite of rooms, simultaneous non-PV work may occur in separate rooms so long as the mitigations outlined in this policy are followed for the PV work room. Poliovirus-essential facilities may have concurrent long-term active non-PV and PV experiments stored in the shared space (*e.g.,* infected cell cultures, animals, tissues), so long as non-PV materials, equipment (*e.g.,* pipettes) and reagents stored in the shared space are not accessed during active PV work, or vice versa. Poliovirus-essential facilities should consider a work pause before and after PV work for decontamination of the shared space.

Poliovirus IM must be segregated from non-PV materials (*e.g.,* in own clearly labeled freezer box, separate freezer racks, lock box) in a secure storage device (*e.g*., incubator, freezer, animal cage racks). Reagents (*e.g.,* phosphate-buffered saline, media) used for PV work must be dedicated to PV work or aliquoted for single use and stored separately from non-PV reagents. Poliovirus-infected small animals may held in the same room as non-PV-infected animals so long as PV-infected animals are housed in a dedicated high-efficiency particulate air (HEPA)-filtered animal cage rack; uninfected and non-PV infected animals in the same room must be housed in separate cage racks.

5.3 Decontamination and waste disposal

5.3.1 Poliovirus-essential facilities must decontaminate all *in vitro* and *in vivo* work surfaces (*e.g.,* benchtops, animal manipulation devices, BSCs, transport containers) and equipment (*e.g,* centrifuges, microscopes) before and after PV work using a decontamination procedure with appropriate contact time validated to inactivate PV (*e.g.,* 10,000 parts per million (ppm) sodium hypochlorite [8] for 5 minutes at 21°C [v] prepared each day of use). As noted in the U.S. NAC RMS, ethyl or isopropyl alcohol does not inactivate PV effectively [vi] and should not be used as a disinfectant. However, a 60-70% alcohol solution can be used after disinfection with sodium hypochlorite, followed by removal of residual hypochlorite with water, to mitigate damage to work surfaces and equipment caused by the sodium hypochlorite.

Poliovirus-essential facilities must remove, treat (*e.g.,* sodium hypochlorite, autoclave), and dispose of all liquid (*e.g.,* culture supernatants) and solid (*e.g.,* contaminated laboratory supplies, PPE) waste generated during PV work from the shared space prior to commencing non-PV work. After removal from shared space, final disposition of liquid and solid waste must be addressed as outlined in the NAC RMS.

Poliovirus-essential facilities must ensure PV materials are secure and not accessible to non-essential personnel. Because PV can survive for extended periods on surfaces [vii, viii] and in PV materials and samples [ix,x] PEFs must ensure that personnel 1) decontaminate all work surfaces, equipment, containers, and contaminated materials using validated methods (*e.g.,* 10,000 ppm sodium hypochlorite [8] for 5 minutes at 21°C [v], prepared each day of use), 2) treat, remove, and discard all PPE appropriately after PV work is completed, and 3) segregate PV reagents and containers storing PV materials.

5.4 Restrict access to PV work and materials

5.4.1 Authorized personnel and training

5.4.1.1. Poliovirus-essential facility must identify and authorize all personnel that require access to shared PV *in vitro* and *in vivo* work and storage area(s) as well PV materials. Poliovirus-essential facilities must confirm up-to-date PV immunization status (*e.g.,* date of immunization or verified antibody titer) for authorized personnel and all personnel entering the shared space. All personnel with access to *in vitro* and *in vivo* shared spaces, including both PV and non-PV personnel, must be trained (*e.g.,* signs and symptoms of infection, route of transmission, asymptomatic PV infection and transmission as well as biosafety, emergency response and security procedures) on all agents handled or stored in the shared space.

5.4.2 Limit access during PV experiments

5.4.2.1. Poliovirus-essential facilities must develop procedures to ensure non-essential personnel cannot access in vitro and in vivo shared spaces when PV work is in progress. Shared space procedures must ensure the entrance to the containment area(s) is secured (e.g., locked door), and visitors requiring access to provide essential services (e.g., maintenance) are escorted by essential personnel. Shared space procedures must also include methods used to alert personnel that PV work is in progress (e.g., signage outside the shared space stating the PV work is in progress). Lastly, poliovirus-essential facilities must document all entries into PV shared space during PV experiments.

5.4.3 Limit access to storage devices

5.4.3.1. Poliovirus-essential facilities must develop procedures to segregate *in vitro* and *in vivo* PV IM in secure storage devices (*e.g.,* locked and dedicated incubator or freezer; lock box within a freezer) that can be accessed by essential personnel only.

Poliovirus-essential facilities procedures must ensure that methods (*e.g.,* passwords, keys) used to open storage devices are unique and available only to essential personnel. Procedures must include updating access methods (*e.g,* inactivating keycards or passwords, returning keys, etc.) following personnel changes, as necessary. Essential personnel must not share the methods used to access

[8] Undiluted bleach contains 52,500-61,500 ppm sodium hypochlorite. Facilities should make a solution of 1-part bleach to 4-parts water to ensure 10,000 ppm is the final concentration.

PV IM with non-essential personnel.

Please contact the U.S. NAC (poliocontainment@cdc.gov) for additional information and guidance.

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	Seventy-first World Health Assembly. Poliomyelitis – containment of polioviruses. May 2018.
ii	Poliovirus Type 3 (PV3) Containment after Declaration of Wild Poliovirus Type 3 (WPV3) Eradication, September 2019.
iii	WHO Containment Certification Scheme
iv	WHO Global Action Plan, 3rd Edition (GAPIII)
v	Chiossone C, Fanuel S, Gedge LM, Nims RW, Suchmann DB, Zhou SS. Inactivation and Disinfection of Poliovirus Type 1 on Nonporous Carriers. *Adv Biotech & Micro.* 2018. 9(5): 96-102.
vi	Klein M, DeForest A. The inactivation of viruses by germicides. *Chem. Specialists Manuf. Assoc. Proc.* 1963. 49:116-8.
vii	Mahl MC, Sadle C. Virus survival on inanimate surfaces. *Can. J. Microbiol.* 1975. 21: 819-823.
viii	Vasickova P, Pavlik I, Verani M, Carducci A. Issues Concerning Survival of Viruses on Surfaces. *Food Environ Virol.* 2010. 2(1):24-34.
ix	Dowdle WR, Birmingham ME. The Biological Principles of Poliovirus Eradication. *J Infect Dis.* Suppl 1. 1997. S286-92.
x	Bae J, Schwab KJ. Evaluation of Murine, Norovirus, Feline Calicivirus, Poliovirus, and MS2 as Surrogates for Human Norovirus in a Model of Viral Persistence in Surface Water and Groundwater. *Appl Environ. Microbiol.* 2008, 74 (2) 477-484.

7. Attachments

None

8. Version History

Version	Change Summary	Effective Date
01	New document	4/21/2020
02	Convert interim guidance (NAC.AUDIT.POL.011.01) to policy.	5/15/2021
03	Document updated to include all PV IM, 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.