Policy for U.S. Poliovirus-Essential Facilities to Control Security of Poliovirus Materials and Information

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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

The U.S. National Authority for the Containment of Poliovirus (NAC) Security policy requires U.S. Poliovirus-Essential Facilities (PEFs) that will apply for an Interim Certificate of Containment (ICC) or a Certificate of Containment (CC) [i] to implement security measures to safeguard poliovirus (PV) materials (*e.g.,* cultures, specimens, samples, potentially contaminated materials, waste) and information including, but not limited to, the conditions stated within this policy. These security measures will help to mitigate the risk of a theft, loss or release of PV materials or information. Poliovirus-essential facilities may adopt additional security control measures based on a site-specific risk assessment. Poliovirus-essential facilities must notify local first responders (*e.g.,* local health, police, and fire departments; private security and commercial waste disposal companies, as appropriate) as well as local, state, and federal agencies annually of PV material possession for their awareness and support of public health surveillance and emergency response, should such be needed.

Please note that this U.S. NAC Security policy (NAC.AUDIT.POL.004.03) supersedes previously published U.S. NAC Security Policy (NAC.AUDIT.POL.004.02).

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) PV potentially infectious materials (PIM) should consider the WHO PIM Guidance document while facilties 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.** [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
CC	Certificate of Containment
CDC	Centers for Disease Control and Prevention
cDNA	Complementary DNA
CP	Certificate of Participation
cVDPV	Circulating vaccine-derived poliovirus
GAPIII	WHO Global Action Plan, Third edition
ICC	Interim Certificate of Containment
IM	Infectious material
IPV	Inactivated polio vaccine
IT	Information technology
NAC	National Authority for Containment of Poliovirus
OPV	Oral polio vaccine
PC	Personal computer
PEF	Poliovirus-essential facility
PI	Principal investigator
PIM	Potentially infectious material
PIN	Personal identification number
PRP	Personnel Reliability Program
PV	Poliovirus
RNA	Ribonucleic acid
UL	Underwriters Laboratories
VDPV	Vaccine-derived poliovirus
WHO	World Health Organization
WPV	Wild poliovirus

4. Definitions

Term	Definition
Circulating VDPV	Vaccine-derived PV isolates for which there is evidence of person-to-person transmission in the community.
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. [ii] Inactivated polio vaccine (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 [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]." [iii] 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]." [iii]

[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)." [iii] 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
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." [iv] **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.**
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 facilities	"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." [iii] U.S. PEFs will possess or be in pursuit of a CP.
Poliovirus materials	Unless a serotype is specifically identified, PV materials refer to IM and PIM, of all three PV serotypes

Term	Definition
Potentially infectious materials	"Faecal 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" [v]
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. Security

5.1 Physical Security

Poliovirus-essential facilities must ensure security "controls are implemented and maintained for the physical security of cultures, specimens, samples and potentially contaminated materials or waste, determined as part of the risk assessment process" for PV containment area(s) and storage unit(s) outside of containment. [*GAPIII subelement 16.1.1*] When designing a security risk assessment, the PEF "should consider: a. the theft or diversion of poliovirus materials or related equipment, documents or data; b. sabotage, including vandalism and tampering; c. break-in and intrusion; d. labor issues and disputes; e. kidnapping and extortion; f. weather-related emergencies (*e.g.,* earthquake, tsunami, flood, tornado, hurricane); g. workplace violence; h. the failure of utilities; i. picketing, occupation and barricade; j. the screening and isolation of suspect packages; k. acts of terrorism; l. civil unrest or war; m. cyberthreats". [*GAPIII guidance 16.1.1*] Please see the U.S. NAC *Biorisk management and risk assessment* and *Storage Outside of Containment* policies for additional information.

Security breaches must be reported, recorded and investigated as accidents and incidents. [*GAPIII guidance 16.1.1*] In the event of an emergency that requires temporary PV material relocation, PEFs should ensure that access is limited only to individuals requiring access to the material and the PV material is transferred in accordance with the U.S. NAC *Transfer* policy. The PEF must notify the U.S. NAC of emergency relocations by emailing poliocontainment@cdc.gov within 24 hours of the occurrence.

Poliovirus-essential facilities must authorize and report PV containment area(s) and storage unit(s) outside of containment to the U.S. NAC on the PEF's CP. Poliovirus-essential facilities must limit access

to the PV containment area(s) to only authorized personnel and visitors. Authorized personnel must comply with PEF vaccination, training, occupational health and personnel reliability policies for access to PV containment area(s). The PEF must ensure that "suppliers, contractors, visitors and subcontractors adhere to the established management systems' requirements and do not compromise the facility's biorisk management." [*GAPIII subelement 16.5*] Poliovirus-essential facilities should develop procedures to periodically review access records to ensure personnel with access are the only individuals entering the containment area(s).

Poliovirus containment area(s) must be enclosed by a permanent barrier from floor to ceiling, with entry doors that can be securely locked. Material used in the construction of the permanent barrier must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. Walls must be permanent construction, floor to ceiling.

Entry door(s) to PV containment area(s) must be secured (*e.g.,* magnetic lock or an UL approved lock and lock cylinder, card access system). In the event of an electronic access system failure (*e.g.,* power outage), locks will remain secure to prevent entry but allow occupants to egress from the facility. External hardware is removed (or lock cores sealed) on all fire exits and other perimeter doors that could create an unauthorized entrance to the PV containment area(s). Facility procedures should establish backup plans for failure of electronic access systems.

5.2 Information Security

Poliovirus-essential facilities must ensure that "a policy and procedure are in place to identify sensitive information." [*GAPIII subelement 16.2.1*] Based on site-specific risk assessment, the PEF must implement "adequate measures to prevent the unauthorized release of such information", including: "a. the secure storage of all sensitive written records and data (*e.g.* virus inventories, security plans, security inspection reports, design drawings, maintenance plans, human resource information including worker contact details), including electronic records and electronic signatures; b. computer security, including robust internet firewalls and encryption protocols; c. strict policies regarding PCs, laptop computers, storage media and cameras, among others, entering or leaving the facility; d. the thorough destruction of paper files to be discarded, and complete erasure of unwanted electronic files." [*GAPIII guidance 16.2.1*] Poliovirus-essential facilities security measures to protect sensitive information may include, but are not limited to, locked, storage devices (*e.g.,* file cabinets); password-protected files, folders, and computers; or stand-alone computers.

Poliovirus-essential facility policy and procedures must ensure that "a review and approval process is used to control access to sensitive information." [*GAPIII subelement 16.2.2*] The PEF must establish procedures that identify personnel requiring access to PV sensitive information and ensure the methods of access (*e.g.,* passwords) are limited to those personnel. Poliovirus-essential facilities should periodically review access records, as applicable, to ensure non-approved personnel or individuals cannot access PV sensitive information. Poliovirus-essential facility policy must ensure that personnel with access to sensitive information do not share their means to access information (*e.g.,* passwords) with other individuals, including personnel who also have access.

5.3 PRP Enrollment

Poliovirus-essential facilities should identify individuals requiring access as part of the PEF risk assessment process. [*GAPIII guidance 16.3.1*] Please see the U.S. NAC *Biorisk management and risk assessment* policy for additional information.

Poliovirus-essential facilities must design and implement a PRP. [*GAPIII subelement 16.3.1*] A PEF PRP must include procedures for screening individuals before providing access to PV laboratory and storage area(s) and associated facility operating systems (*e.g.,* heating, ventilation, and air conditioning; effluent decontamination system), IM and PIM, and sensitive information (*e.g.,* inventory records information technology (IT) systems capable of granting access to PV laboratory and storage area(s)). The PRP must also include 1) ongoing reliability assessments to continually assess personnel requiring access, 2) procedures for reporting of PEF rules of behavior, and 3) measures to ensure that all individuals with access are trained on the PEF's PRP. [*GAPIII subelement 16.3.2*]

All individuals granted independent access including persons requiring access to PV laboratories for non-PV work, must be enrolled in the PEF PRP. Poliovirus-essential facilities should determine individual access based on the roles and responsibilities.

- Individuals requiring access to sensitive information (*e.g.,* IT support staff tasked with programming badges and PINs) must be enrolled in the PEF PRP before access to the information is granted.
- Individuals and visitors not enrolled in the PRP (*e.g.,* auditors, technicians hired to perform biosafety cabinet certifications) must be escorted by an individual who is enrolled in the PEF PRP when accessing PV sensitive information, area(s), and materials.
- Individuals (*e.g.,* students, visiting scientists, contractors) who require independent access but may not be employed by the PEF directly are subject to the PEF PRP.

5.4 PRP Consultation with Legal and Human Resources

The PRP should be developed in accordance with GAPIII, PEF policies and applicable federal, state, and local employment and privacy laws. Poliovirus-essential facilities should consider legal and human resources consultation for all aspects of a PRP including, but not limited to:

- Identifying criteria for pre-access screening and ongoing reliability assessments.
- Developing position descriptions, including personnel reliability requirements.
- Creating processes to review and adjudicate information collected for pre-access screens, ongoing reliability, cases of individuals who are unable or unwilling to adhere to PEF policies and procedures, and reports of PEF rules of behavior, violations.
- Establishing criteria and procedures for revoking and restoring access for individuals who are unable or unwilling to adhere to criteria established in the PEF PRP, or who violate PEF rules of behavior.
- Identifying personnel and procedures to review ongoing reliability and reports of violations of PEF rules of behavior. Personnel must objectively perform these tasks and enforce requirements without a conflict of interest.
- Using existing performance mechanisms to assess ongoing reliability.

5.5 PRP Pre-Access Screening Criteria

Poliovirus-essential facilities must have a pre-access screening assessment for all individuals who will be granted independent access to PV sensitive information and laboratory areas. A PEF must ensure that individuals not employed directly by the PEF (*e.g.,* students, visiting scientists, contractors) are pre-screened before independent access is granted.

Poliovirus-essential facilities should collect and verify the following pre-access screening information, either directly or in conjunction with their human resources department [*GAPIII guidance 5.1.1*]:

- References (*e.g.,* previous supervisors, non-family acquaintances);
- Education and professional credentials;
- Current and prior residences;
- Prior laboratory experience;
- Other information, as identified by PEF hiring policies and risk assessment.

The PRP must describe the processes and criteria used to approve access.

5.6 PRP Ongoing Reliability Criteria

The PRP must include procedures to ensure the ongoing reliability assessment of all individuals granted access, regardless of when access was approved. Poliovirus-essential facilities may use existing periodic performance review mechanisms (*e.g.,* annual performance evaluations) to assess reliability, including rating the individual's adherence to PEF) biosafety and security procedures, 2) laboratory competency standards and "good microbiological techniques" [*GAPIII subelements 5.3 and 6.1*], and 3) rules of behavior. [*GAPIII element 8*] Individuals (*e.g.,* students, visiting scientists, contractors) who require independent access but may not be employed by the PEF directly are subject to ongoing reliability assessments as performed by the employer (Note: PEFs should provide guidance to assist contracting companies in developing and managing reliability assessment programs). Poliovirus-essential facilities should identify an office within the institution that determines employee suitability. Contracting company reliability assessments must meet, at a minimum, the reliability criteria determined by the facility.

The PRP must address risk associated with human behavior. Poliovirus-essential facilities must employ measures to address "team building and motivation, conflict management and resolution, management of stress and fatigue, access to counseling, avoidance of a "blame culture", and respect for individual privacy and dignity". Poliovirus-essential facilities should consider ensuring personnel with access have access to existing employee assistance programs. [*GAPIII guidance 8.1.1*]

5.7 PRP Procedures for Behaviors of Concern and Negative Information

Poliovirus-essential facilities must develop avenues of communication for individuals at the PEF to report behaviors of concern and violations of PEF rules of behavior. [*GAPIII guidance 8.1.1*] Poliovirus-essential facilities should allow anonymous reporting (*e.g.,* whistleblower hotline or other reporting mechanism). Poliovirus-essential facilities must also develop procedures to collect and evaluate information regarding staff who are unable or unwilling to adhere to criteria established in the PEF PRP.

Poliovirus-essential facilities must revoke access for individuals who do not meet ongoing reliability

assessment and rules of behavior criteria as established by the PEF. Poliovirus-essential facilities must establish a process to review information for rules of behavior violations reported by personnel or collected during assessments. The process must include the PEF staff (*e.g.,* Human Resources Coordinator or Manager) responsible for reviewing and adjudicating each case. The procedures should also include criteria for revoking access and restoring the access if the issues are resolved, processes for individuals to respond to allegations, protections for retaliation from individuals exhibiting or reporting behaviors of concern, and procedures for protecting confidential information. [*GAPIII guidance 5.5.1*]

5.8 PRP Training

Poliovirus-essential facilities must provide training to all individuals enrolled in the PRP. The PRP training should address all aspects of the PEF's PRP including biosafety and security procedures, PPE requirements, good microbiological techniques and laboratory standards, personnel security awareness, rules of behavior, and mechanisms for reporting violations of the PEF rules of behavior. Poliovirus-essential facilities must provide and document the training at least annually and develop measures to assess PRP training effectiveness (*e.g.,* quiz, competency assessment). [*GAPIII subelement 5.2.1*]

5.9 Records of Access

Poliovirus-essential facilities must implement measures to record all entries into PV containment area(s), effluent decontamination system areas, or unit(s) storing PV materials outside of PV containment. [*GAPIII subelement 1.4, subelement 16.1.1 guidance*] Access records must include the first and last name of the individual entering the area and date and time of entry. Poliovirus-essential facilities must also record visitor first and last name, date and time of entry, and escort name (if applicable). Access record verifications should be performed periodically (*e.g.,* quarterly) to ensure only authorized personnel are accessing the PV containment area(s).

Poliovirus-essential facilities must develop chain-of-custody forms and procedures to track and document intra-facility transfers. Please see the U.S. NAC *Storage Outside of Containment* and *Transfer* policies for additional information.

Records of access may be "maintained in paper or electronic form" so long as PEF procedures ensure records "remain legible, readily identifiable and retrievable". [*GAPIII subelement 1.4.2*] Poliovirus-essential facilities must maintain records of access "for a minimum of 10 years from the day of withdrawal and should be available for review during national certification/WHO verification procedures." [*GAPIII subelement 1.4.2*] Poliovirus-essential facilities must develop procedures to ensure storage of access records, documents and data are "controlled and maintained to provide evidence of conformity". [*GAPIII subelement 1.4.1*] For PEFs that maintain electronic access records, backup procedures should be developed to ensure access is recorded in the event of a power outage or system malfunction.

Poliovirus-essential facilities that utilize PV containment area(s) for non-PV work must document access during PV experiments. Records of access must document the time period(s) (*e.g.,* months) in which PV experiments are performed. Please see the U.S. NAC *Policy for shared use of U.S. poliovirus-essential facilities* for additional information on regulating access to containment area(s) and storage unit(s).

6. References

6.1 Internal References

Reference
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)
U.S. NAC *Policy for U.S. Facilities to Store Poliovirus Materials Outside of WHO GAPIII Containment* (Storage Outside of Containment Policy)
U.S. NAC *Policy for shared use of U.S. poliovirus-essential facilities* (Shared Use Policy)

6.2 External References

#	Reference
i	WHO Containment Certification Scheme
ii	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.
iii	WHO Global Action Plan, 3rd Edition (GAPIII)
iv	WHO Containment Activity Group, Report of the Second Meeting of the Containment Advisory Group, November 2017
v	World Health Organization. Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses. 2018

7. Attachments

None

8. Version History

Version	Change Summary	Effective Date
01	New document	12/6/2018
02	Changed policy name from Physical Security to Security; PV material covered under this policy; application of pre-access screen to all personnel. Consolidates previous Physical Security, PRP, and Record of Access policies into one policy. Added GAPIII requirements to safeguard sensitive information and passwords, keys, etc. required to access information and material; chain-of-custody forms and procedures to track intra-entity transfers. Removes the transfer of personnel screening if individual has access at more than one facility. Reformatted to include cover sheet, table of contents, and definitions. Clarified risk mitigation issues observed by U.S. NAC auditors during site visits.	5/1/2021
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.