

# Guidance for Importation of Polioviruses and Potentially Infectious Materials

**Christy Ottendorfer, PhD**

**Microbiologist/Senior Science Advisor**

Import Permit Webinar

December 2, 2021



# Overview

- Polio eradication update
- Poliovirus containment
  - Poliovirus material types
  - WHO Global Action Plan
  - WHO Guidance for Potentially Infectious Materials (PIM)
  - Imported Poliovirus Materials, USA 1996-2021
  - U.S. NAC Guidance for Imported Poliovirus Materials
- Conclusions

# Acronyms

CC	Certificate of Containment	PEF	Poliovirus-essential facility
CP	Certificate of Participation	PIM	Potentially infectious materials
cVDPV	Circulating Vaccine Derived Poliovirus	PV	Poliovirus
GAP	Global Action Plan, 3rd edition	VDPV	Vaccine-derived poliovirus
GCC	Global Commission for Certification Polio Eradication	WHO	World Health Organization
GPEI	Global Polio Eradication Initiative	WPV	Wild poliovirus
ICC	Interim Certificate of Containment		
IM	Infectious materials		
IPP	Import Permit Program		
OPV	Oral polio vaccine		
- bOPV	Bivalent oral polio vaccine (types 1, 3)		
- mOPV	Monovalent oral polio vaccine		
- nOPV	Novel oral polio vaccine		
- tOPV	Trivalent oral polio vaccine (types 1, 2, 3)		

# Polio Eradication Update

# Wild Poliovirus Eradication Update

We're **zeroing in** on polio, one viral strain at a time.

Type 2



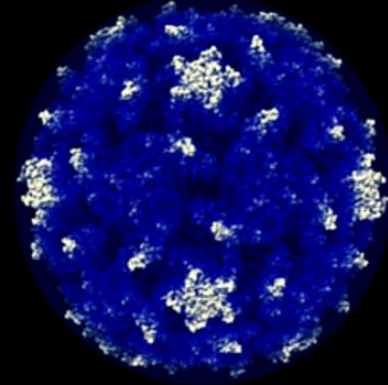
Last seen 24 Oct 1999  
**Declared eradicated**  
20 Sept 2015

Type 3



Last seen 10 Nov 2012  
**Declared eradicated**  
17 Oct 2019

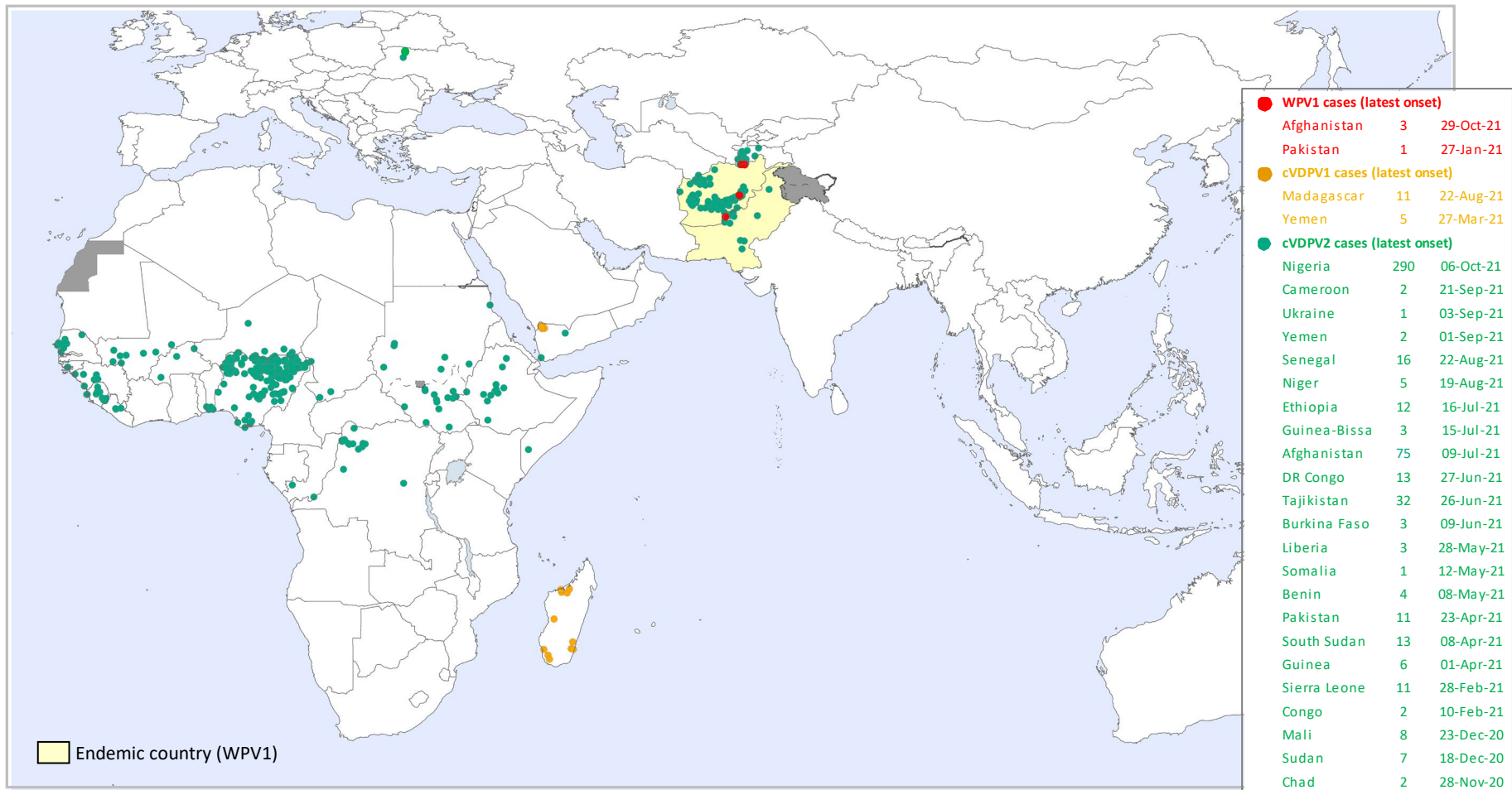
Type 1



It's next

**#endpolio**

# Global WPV1 & cVDPV Cases<sup>1</sup>, Previous 12 Months<sup>2</sup>

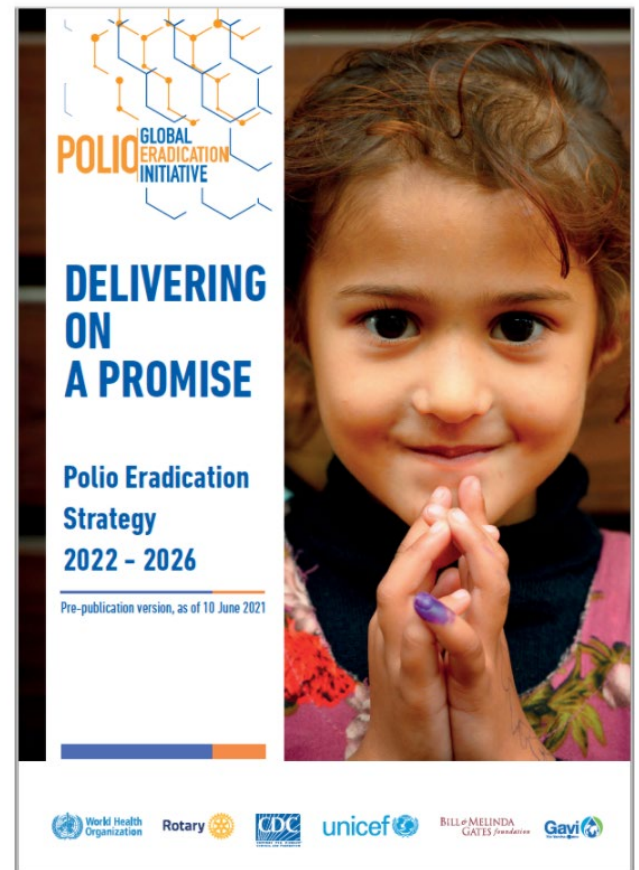


<sup>1</sup>Excludes viruses detected from environmental surveillance; <sup>2</sup>Onset of paralysis 24 Nov. 2020 to 23 Nov. 2021

Data in WHO HQ as of 23 Nov.

# Polio Endgame Strategy

- Recently published new strategy & timeline
- Recognizes impact of COVID-19 pandemic
- Improve political advocacy and vaccine acceptance in endemic countries
- Improve quality of immunization campaigns
- Stop cVDPV outbreaks
  - Pivot from OPV/Sabin vaccine to nOPV2
- PV containment is a focus area of the post-certification strategy



Source: GPEI

<https://polioeradication.org/gpei-strategy-2022-2026/>

# **Poliovirus Containment**

## **... the other half of eradication**



# Introduction to Containment

- Certification of a polio-free world requires containment
- Prevent reintroduction of polioviruses into community from laboratories or vaccine manufacturers
- Implement stringent biosafety and security standards

## 4 PILLARS OF POLIOVIRUS CONTAINMENT



**Identify:** All countries survey their laboratories and other facilities to identify infectious and potentially infectious poliovirus materials



**Destroy:** All countries request that laboratories and facilities destroy all unneeded poliovirus materials



**Transfer:** Laboratories and facilities may choose to transfer needed poliovirus materials to designated poliovirus-essential facilities



**Contain:** Countries will designate poliovirus-essential facilities for continued work with poliovirus type 2. These facilities are expected to comply with the World Health Organization Global Action Plan requirements.

# Poliovirus Material Types – WPV, VDPV, OPV/Sabin

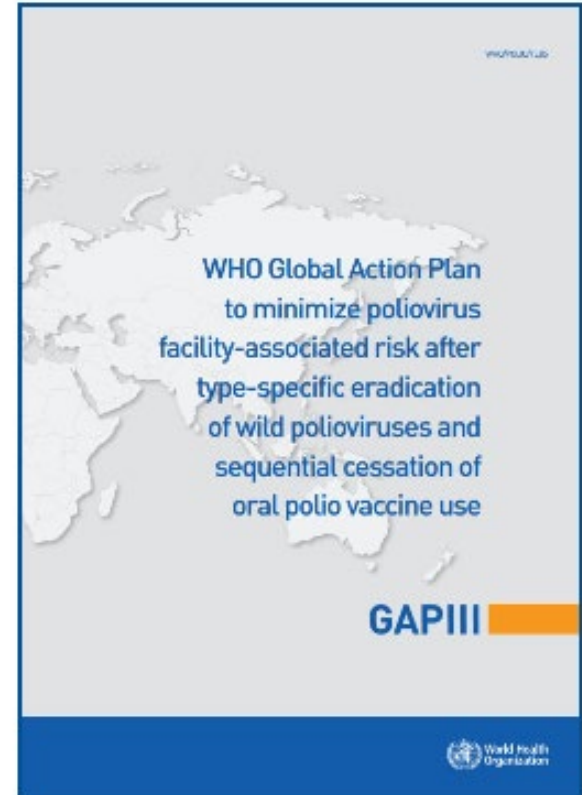
- Infectious Materials
  - PV cell cultures, seed stocks
  - PV+ specimens
  - PV-infected animals
  - Stool, respiratory specimens collected from recent OPV recipients
  - Nucleic acids containing PV capsid sequence
  - Derivatives of these materials

# Poliovirus Material Types – WPV, VDPV, OPV/Sabin PIM

- Potentially Infectious Materials (PIM)
  - **Stool or respiratory secretion samples and their derivatives** collected for any purpose in a **geographic area** where WPV/cVDPV is present or OPV/nOPV 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 as above
  - **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
  - **Environmental samples** (*i.e.* concentrated sewage, wastewater) collected from areas above

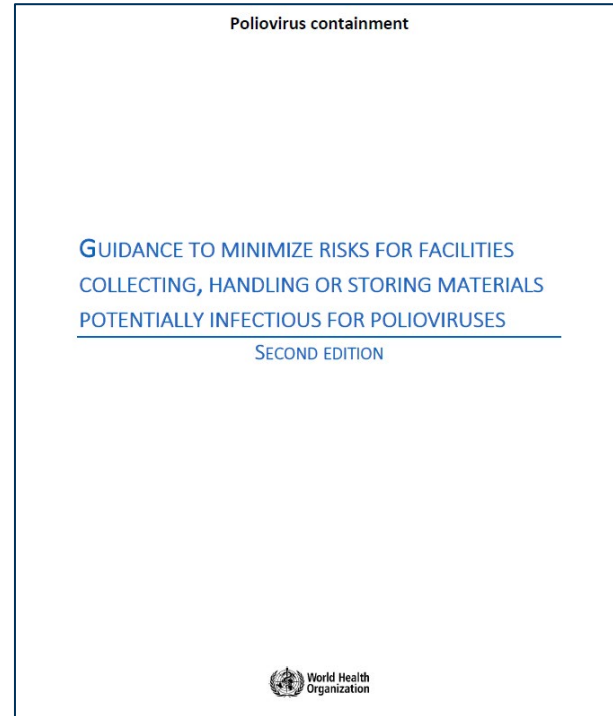
# Global Action Plan (GAPIII) for Poliovirus Containment

- GAPIII published by WHO in 2014
- Defines a strategy to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and cessation of oral polio vaccine use
- 16 technical element/requirement categories for containment
- **PV2, WPV3 and VDPV3 infectious materials may only be handled & stored in certified poliovirus-essential facilities (PEFs)**



# WHO PIM Guidance for work with OPV/Sabin PIM

- Risk classification
  - Based on sample type (stool/sewage, respiratory, nucleic acid) and work (use with PV permissive cells)
- Storage
  - Segregate and secure samples in locked freezer or laboratory
  - Limit access
- Work
  - Mitigations dependent on risk and include risk assessment, good laboratory practices, validation of methods, PV-immunization of staff



# Recent WHO Updates

- GAP revision in progress
  - Release for public comment
  - Anticipated early 2022
  
- PIM guidance updates
  - Address cVDPV outbreaks
  - WPV/VDPV PIM remains subject to GAP containment
  - New PIM digital tool available at <https://worldhealthorg.shinyapps.io/pim-app/>

## Poliomyelitis – containment of polioviruses

The Seventy-first World Health Assembly,

Having considered the report on eradication of poliomyelitis;<sup>1</sup>

Recalling resolution WHA65.5 (2012) on poliomyelitis: intensification of the global eradication initiative and WHA68.3 (2015) on poliomyelitis, and in which the Health Assembly urged all Member States inter alia to implement appropriate containment of all polioviruses starting with the serotype 2;

Noting the eradication of wild poliovirus type 2 globally, declared by the Global Commission for the Certification of the eradication of poliomyelitis in September 2015;

Acknowledging the continued progress in eradicating poliovirus types 1 and 3;

Recognizing the successful globally synchronized switch in April 2016 from the use of trivalent to bivalent oral polio vaccine, active only against poliovirus types 1 and 3;

Noting the development of the Polio Eradication and Endgame Strategic Plan 2013–2018, including objective 3 – containment and certification, considered by the Sixty-sixth World Health Assembly;<sup>2</sup>

Commending the work of WHO and the Global Commission for the Certification of the eradication of poliomyelitis in promoting the containment of all polioviruses, starting with type 2, the first serotype being eradicated;

Noting with alarm delays in implementation and certification of poliovirus containment for type 2 polioviruses planned for 2016, as well as the accidental release of wild poliovirus type 2 from a vaccine-production facility in 2017;

Underscoring the urgent need to accelerate globally activities to implement and certify containment of polioviruses;

Underlining that successful containment of all polioviruses will ensure the long-term sustainability of the eradication of poliomyelitis,

<sup>1</sup> Document A71/26.

<sup>2</sup> Document WHA66/2013/REC/3, summary records of the ninth meeting of Committee A, section 1.

# Poliovirus Importation to USA, 1996-2021

# Summary PV/Enterovirus Permit Requests, 1996-2021<sup>+</sup>

- 209 permit requests for materials infected/potentially infected with enteroviruses (*i.e.*, poliovirus)
  - Peak in 2016 with 41 applications
- 58 countries listed as source of material imported
  - 82 applications listed multiple countries
- Permittees located in 27 states<sup>++</sup>

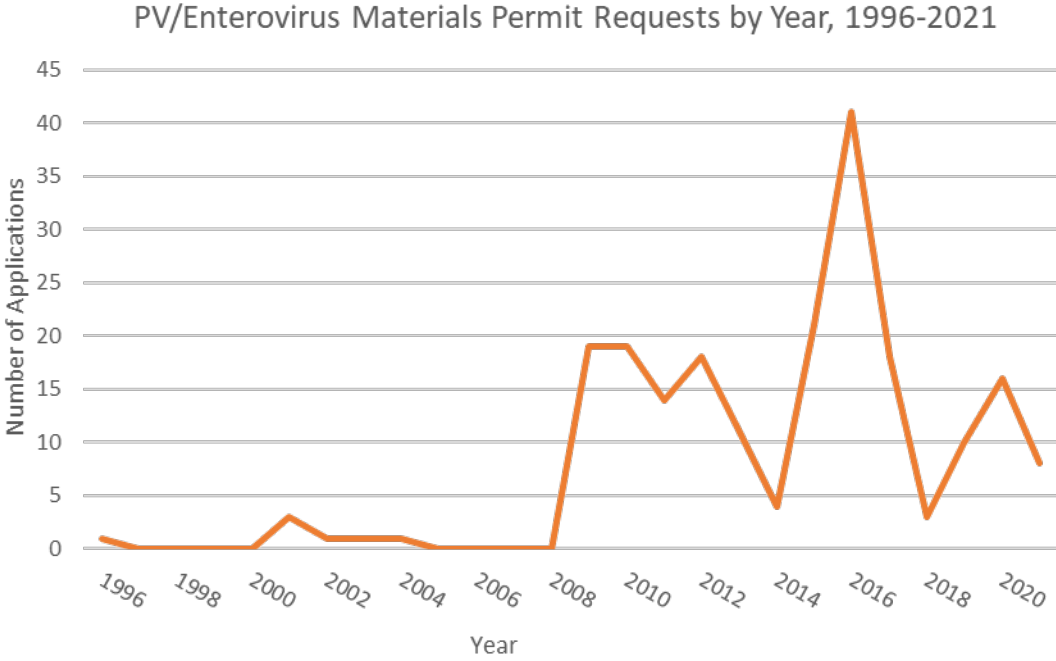
<sup>+</sup>Data source: CDC Import Permit Program records

<sup>++</sup>Complete data set available for 179 of 209 applications



# PV Permit Applicants by Year, 1996- Oct 2021

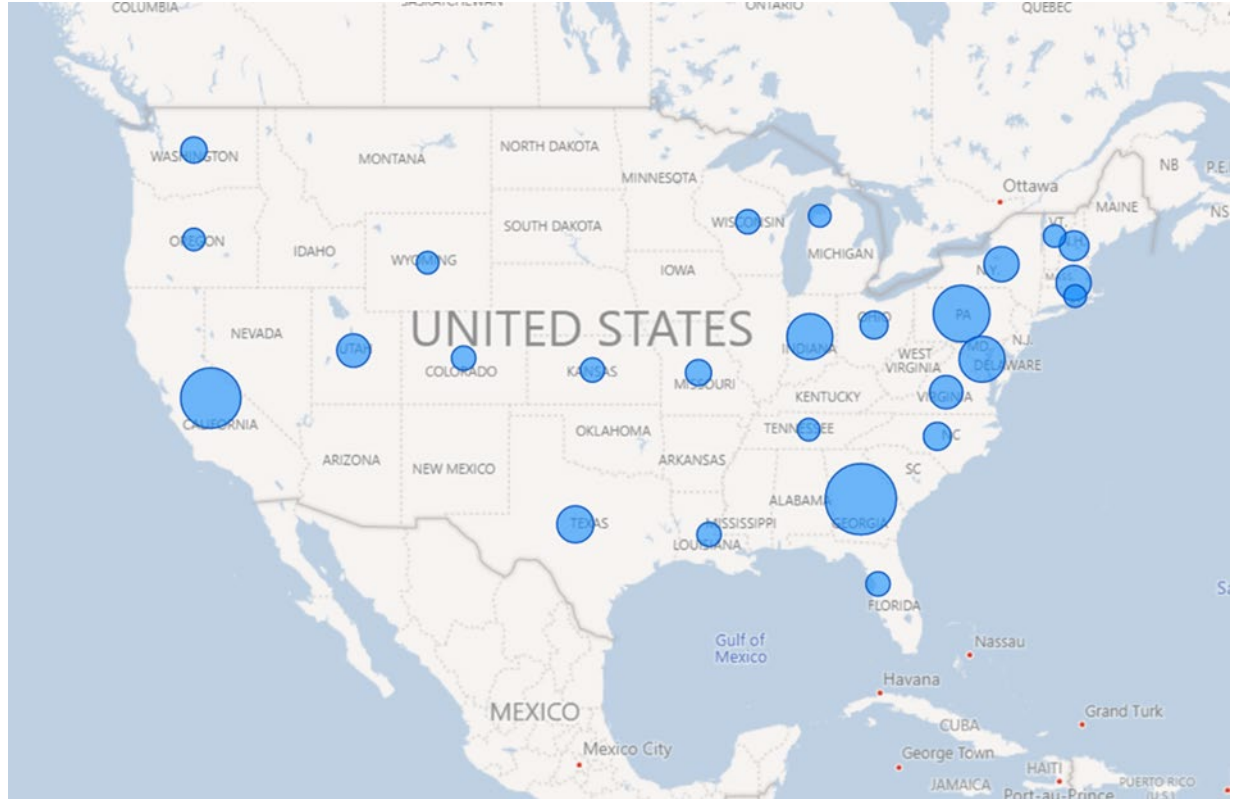
Year of Application	Number of Applications
1996	1
2001	3
2002	1
2003	1
2004	1
2009	19
2010	19
2011	14
2012	18
2013	11
2014	4
2015	21
2016	41
2017	18
2018	3
2019	10
2020	16
2021	8
<b>Grand Total</b>	<b>209</b>



The table to the left and graph above indicate the number of poliovirus/enterovirus materials import permits requested by year from 1996 to Oct 2021.

# PV Permit Applicants by State, 1996 – Oct 2021

State of Applicant	Number of Applications by State
GA	28
CA	22
PA	20
IN	14
MD	14
TX	9
MA	8
NY	8
HI	7
UT	7
VA	7
NH	5
NC	4
OH	4
MO	3
WA	3
CO	2
KS	2
LA	2
WI	2
FL	2
MI	1
VT	1
OR	1
WY	1
RI	1
TN	1
<b>Total Applications</b>	<b>179</b>



The table and map above indicate the geographical distribution of the applicants requesting to import poliovirus-infected or potentially infectious material on behalf of their organization by US state. 30 applications were excluded due to missing data.

# Country of Origin for Imported Material, 1996 – Oct 2021



The map above shows the distribution of countries that were listed by applicants as the source of poliovirus/enterovirus- and potentially-infectious materials being requested, 1996-2021.

# **U.S. NAC Guidance for Imported Poliovirus Materials**

# U.S. Guidance – Poliovirus Import Permit Process

- For permits requesting PV or specimens that may contain PV:
  - Import Permit staff will request confirmation that your institution has contacted U.S. NAC
  - Import Permit staff will notify U.S. NAC of application
  - U.S. NAC confirms your institution's participation in national survey with you and your biosafety officer
  - U.S. NAC may request additional documentation once materials are imported (*e.g.*, compliance with applicable WHO poliovirus containment standards)

# U.S. NAC Website – Poliovirus Containment Survey

- NAC must identify U.S. facilities with poliovirus materials
- Facility submits survey to report any poliovirus IM and PIM
  - Includes OPV/Sabin & nOPV that may not require import permit
- Facility maintains inventory of PV materials
- Facilities with PV2, WPV3/VDPV3 IM participate in containment certification to become **poliovirus-essential facilities**

U.S. National Authority for Containment of Poliovirus

National Inventory for Poliovirus Containment

Public Health Laboratories Vaccine Producers Research Laboratories Clinical Laboratories Storage Facilities Environmental Testing Laboratories

Find out if your institution should take the NIPC today!

Polio Disease & Poliovirus National Inventory for Poliovirus Containment

The Need for Containment Past Surveys of U.S.

CDC Centers for Disease Control and Prevention

U.S. National Authority for Containment of Poliovirus

Center for Preparedness and Response > Poliovirus Containment

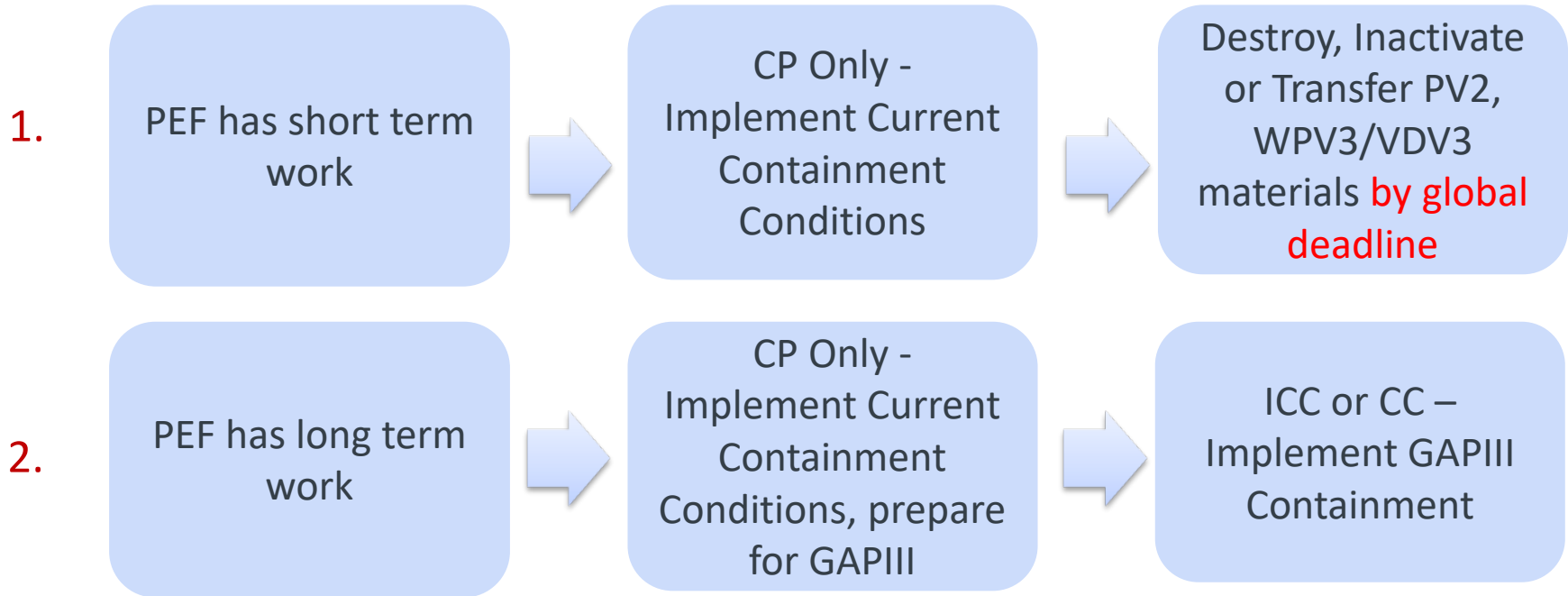
### National Inventory for Poliovirus Containment: Minimizing Risk of Poliovirus Release from Laboratories in the United States

The US Poliovirus National Authority for Containment of Poliovirus (NAC), located in the Centers for Disease Control and Prevention, Center for Preparedness and Response, appreciates your participation in this survey. This survey is designed to collect relevant laboratory inventory data to ensure compliance with requirements established in the [WHO Global Action Plan \(GAPIII\)](#), as adapted for the WHO Region of the Americas. Per GAPIII, each country is required to complete a national inventory of poliovirus-containing materials. Unlike previous surveys, the 2018 survey focuses on institutions that may have poliovirus potentially infectious materials (PIM). PIM includes human respiratory secretions and fecal specimens collected for non-polio related work in a time and place where wild poliovirus (WPV) or vaccine-derived poliovirus (VDPV) was circulating or where oral polio vaccine (OPV) was in use. Historical domestic and international specimens are more likely to fall into these categories. Additionally, PIM cultured in some common cell lines (see Appendix C: Common Cell Lines and Animals Susceptible to Poliovirus) in order to isolate other viruses of interest may

On This Page
Survey Overview
Survey Instructions
National Inventory for Poliovirus Containment Survey
Appendices
Appendix D
Reference Documents

[https://www.cdc.gov/cpr/polioviruscontainment/surveys\\_laboratories.htm](https://www.cdc.gov/cpr/polioviruscontainment/surveys_laboratories.htm)

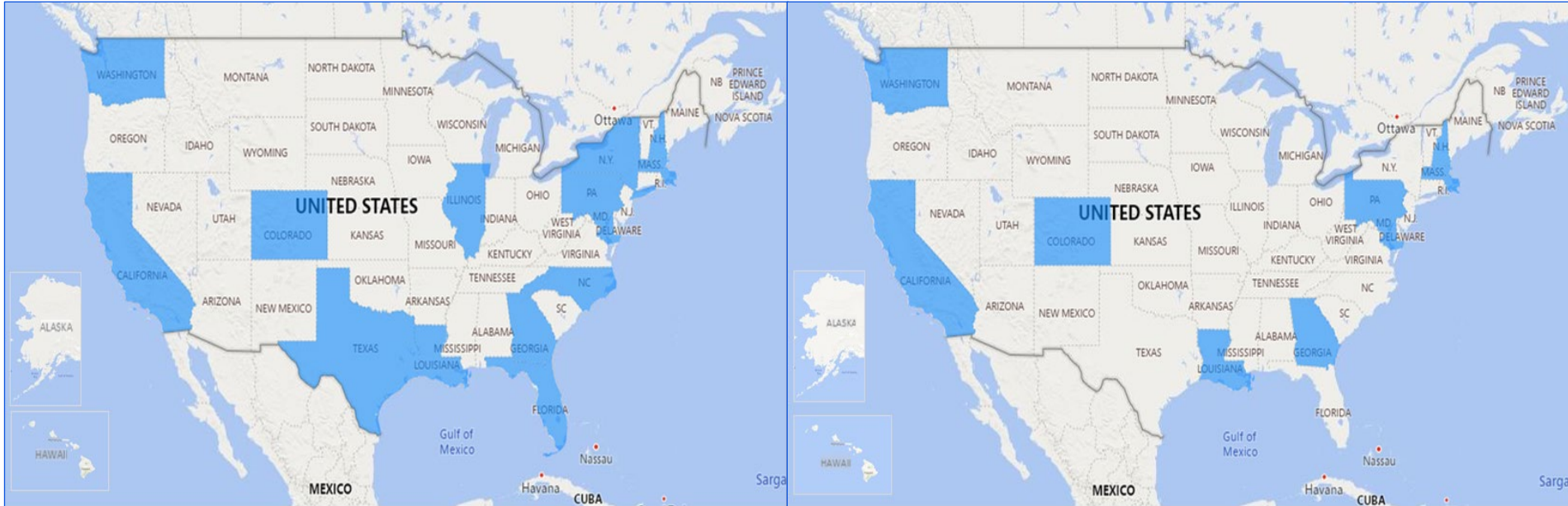
# U.S. Guidance – If you import Infectious Materials<sup>+</sup>: Two Paths for PEF Certification<sup>++</sup>



<sup>+</sup>Excludes PV1, OPV3 at this time

<sup>++</sup>CP - Certificate of Participation, ICC – Interim Certificate of Containment, CC – Certificate of Containment

# U.S. states hosting Poliovirus-Essential Facilities between 2017 – 2021



**2017 – 2020 (n=14)**

**October 2021 (n=9)**



# U.S. Guidance – If you import PV PIM:

## Strategies for Retained PIM

N/A	Wild PV (WPV) or vaccine-derived PV (VDPV) PIM	Oral polio vaccine (OPV) PIM
Definition*	At risk of containing WPV or VDPV	At risk of containing OPV
Storage	Segregate from non-PIM Secure samples in locked freezer or laboratory, limit access	Segregate from non-PIM Secure samples in locked freezer or laboratory, limit access
Work	Contact US NAC for work with WPV PIM at <a href="mailto:poliocontainment@cdc.gov">poliocontainment@cdc.gov</a>	Follow risk mitigations as detailed in PIM Guidance
When	WPV2 and WPV3 PIM now WPV1 PIM in the future	tOPV <sup>i</sup> and mOPV2 <sup>ii</sup> PIM now bOPV <sup>iii</sup> PIM in the future

\*Includes derivatives of these samples (e.g., stool suspensions, extracted nucleic acids)

i)OPV = trivalent containing OPV1, 2 and 3; ii)OPV = monovalent containing only OPV2; iii)OPV = bivalent containing OPV1 and 3

## U.S. Guidance – What to do when work is complete

- Once work is completed with PV materials, determine if material is still essential
- If essential, continue to **CONTAIN**
- If non-essential
  - **CONTACT** U.S. NAC for required documentation
  - **DESTROY** material by autoclave or incinerator
  - **INACTIVATE** material using a validated method
  - **TRANSFER** material to an approved laboratory

# Conclusions

# Key Messages

- Import Permit team coordinates with NAC for PV IM and PIM requests
- Complete national survey for PV materials
  - Periodically survey laboratories for PV IM and PIM
  - Review activities with international specimen collections and submit inventory updates, when applicable
  - New WHO digital tool available to help identify PIM
- Maintain inventory of PV materials and report updates to NAC
- Enhance containment practices for work and storage of these materials
- Contact U.S. NAC for questions or guidance on PV materials
- Your continued support of poliovirus containment safeguards the global polio eradication effort

*For more information, contact the U.S. NAC at*

404-718-5160

[poliocontainment@cdc.gov](mailto:poliocontainment@cdc.gov)

[www.cdc.gov/cpr/polioviruscontainment/index.htm](http://www.cdc.gov/cpr/polioviruscontainment/index.htm)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

