**Poliovirus containment**

FORM 1: Facility reporting form

19 September 2018

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# Abbreviations and Acronyms

CCS GAPIII Containment Certification Scheme

GAPIII Global Action Plan III for Poliovirus Containment

GCC Global Commission for the Certification of the Eradication of Poliomyelitis

IM Infectious material

MoH Ministry of Health

NAC National authority for containment

NCC National Certification Committee for Poliomyelitis Eradication

NPCC National Poliovirus Containment Coordinator

NTFC National Task Force for Containment

OPV Oral polio vaccine

bOPV Bivalent oral polio vaccine (containing Sabin poliovirus type 1 and type 3)

mOPV Monovalent oral polio vaccine (containing one type of Sabin poliovirus)

mOPV1 Monovalent oral polio vaccine type 1

mOPV2 Monovalent oral polio vaccine type 2

mOPV3 Monovalent oral polio vaccine type 3

OPV1 Oral polio vaccine type 1

OPV2 Oral polio vaccine type 2

OPV3 Oral polio vaccine type 3

tOPV Trivalent oral polio vaccine (containing Sabin poliovirus type 1, type 2 and type 3)

PEF Poliovirus-essential facility

PIM Potentially infectious material

PV Poliovirus

PV1 Poliovirus type 1

PV2 Poliovirus type 2

PV3 Poliovirus type 3

VDPV Vaccine-derived poliovirus

VDPV1 Vaccine-derived poliovirus type 1

VDPV2 Vaccine-derived poliovirus type 2

VDPV3 Vaccine-derived poliovirus type 3

WHO World Health Organization

WPV Wild poliovirus

WPV1 Wild poliovirus type 1

WPV2 Wild poliovirus type 2

WPV3 Wild Poliovirus type 3

# Declarations

This reporting form should be used by the facility when reporting the identification, destruction or retention of poliovirus infectious or potentially infectious material (PV IM or PIM) to their National Poliovirus Containment Coordinator (NPCC), National Certification Committee for Poliomyelitis Eradication (NCC), National Task Force for Containment (NTFC), or responsible national authority e.g., Ministry of Health, or equivalent.

Please complete ALL sections of this form.

**NOTE**: A facility is defined**[[1]](#footnote-1)** as any site (e.g. laboratory, repository or vaccine production unit) owned or operated by any level of government, academic institution, corporation, company, partnership, society, association, firm, sole proprietorship or other legal entity.

This form is completed and submitted for:

|  |  |
| --- | --- |
| Name of the facility: |  |
| Address: |  |
| Country: |  |
| Date of submission: |  |
| Reporting period: |  |

|  |  |
| --- | --- |
| I have read the WHO *[Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)* (PIM Guidance) and I am applying it to provide the information requested in this form. | Yes  No  N/A |
| I have followed the PIM e-tool available on the web to provide the information requested in this form. | Yes  No  N/A |
| I have completed ALL sections in this form. | Yes  No  If no, please explain[[2]](#footnote-2): |

Name, designation and affiliation of the person **completing** this form:

|  |  |
| --- | --- |
| Name: |  |
| Designation: |  |
| Affiliation: |  |
| Address: |  |
| Country: |  |
| E-mail: |  |
| Telephone n°: |  |
| Signature: |  |
| Date: |  |

Name, designation and affiliation of the person **approving** this report (i.e. Director of the facility):

|  |  |
| --- | --- |
| Name: |  |
| Designation: |  |
| Affiliation: |  |
| Address: |  |
| Country: |  |
| E-mail: |  |
| Telephone n°: |  |
| Signature: |  |
| Date: |  |

Please submit this completed form and any relevant attachments to:

|  |  |
| --- | --- |
| Name: |  |
| Designation: | NPCC  NTF Chair  Other  If other, please specify: |
| E-mail: |  |
| Mailing address: |  |
| Telephone n°: |  |
| Date of submission: |  |

# 1. Identification, destruction or retention of WPV/VDPV infectious or potentially infectious material (WPV/VDPV IM or PIM)

## WPV/VDPV infectious material (IM):

**NOTE**: WPV/VDPV IM include clinical materials from confirmed infections; environmental sewage or water samples that have tested positive for the presence of these viruses; cell culture isolates and reference strains of these viruses; 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 WPVs, unless demonstrably proven to be safer than Sabin strains; cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus; as described in the WHO *Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use* ([GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)).

Following [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), I conclude that:

The facility **does not** retain any WPV/VDPV **IM,** as follows (please check all that applies):

|  | WPV/VDPV IM | WPV/VDPV IM | | | |
| --- | --- | --- | --- | --- | --- |
|  | Have never been possessed  (tick box if applicable) | Have been destroyed on (please indicate the latest date as dd/mm/yyyy) | Have been inactivated using a method known to inactivate poliovirus on (please indicate the latest date as dd/mm/yyyy) | Have been transferred to a PEF on (please indicate the PEF and the latest date as dd/mm/yyyy) |
| 1. | WPV1/VDPV1[[3]](#footnote-3) |  |  |  |  |
| 2. | WPV2/VDPV2[[4]](#footnote-4) |  |  |  |  |
| 3. | WPV3/VDPV3[[5]](#footnote-5) |  |  |  |  |
| 4. | PV nucleic acid[[6]](#footnote-6) |  |  | N/A | N/A |

The facility **retains** WPV/VDPV **IM**, as follows:

|  | WPV/VDPV IM | WPV/VDPV IM are retained (please briefly describe the rationale) |
| --- | --- | --- |
| 1. | WPV1/VDPV1 |  |
| 2. | WPV2/VDPV2 |  |
| 3. | WPV3/VDPV3 |  |
| 4. | PV nucleic acid |  |

The retention of WPV/VDPV IM is subject to the approval of the responsible national authority (e.g. MoH) and to the facility’s implementation of containment requirements described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), assessed and certified by the national authority for containment (NAC) and the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC), following the *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment* ([CCS](http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf)).

PV nucleic acid extracted from WPV/VDPV IM using methods demonstrated to inactivate poliovirus, or synthesized RNA, or complementary DNA (cDNA) can be handled outside of PV containment under the condition that these materials will not be introduced into PV-permissive cells or animals with or without a transfection reagent, except under appropriate containment conditions as described in GAPIII.

## WPV/VDPV potentially infectious material (PIM):

**NOTE:** WPV/VDPV PIM include faecal, respiratory tract, or concentrated sewage samples collected for any purpose in a time and geographic area of WPV/VDPV circulation, identified as PIM following the WHO *Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses* and its associated *Annex 2* ([PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)); products of such materials from poliovirus permissive cells or animals; uncharacterized enterovirus-like cell culture isolates from countries known or suspected to have circulating WPV/VDPV at the time of collection; respiratory and enteric stocks handled under conditions where poliovirus contamination or replication is possible; as described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/).

Following the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), I conclude that:

The facility **does not** retain any WPV/VDPV **PIM**, as follows (please check all that applies):

|  | WPV/VDPV PIM | WPV/VDPV PIM | | | |
| --- | --- | --- | --- | --- | --- |
|  | Have never been possessed  (tick box if applicable) | Have been destroyed on (please indicate the latest date as dd/mm/yyyy) | Have been inactivated using a method known to inactivate poliovirus on (please indicate the latest date as dd/mm/yyyy) | Have been transferred to a PEF on (please indicate the PEF and the latest date as dd/mm/yyyy) |
| 1. | WPV1/VDPV1 |  |  |  |  |
| 2. | WPV2/VDPV2[[7]](#footnote-7) |  |  |  |  |
| 3. | WPV3/VDPV3 |  |  |  |  |
| 4. | PV nucleic acid |  |  | N/A | N/A |

The facility **retains** WPV/VDPV **PIM**, as follows:

|  | WPV/VDPV PIM | WPV/VDPV PIM are retained (please briefly describe the rationale) |
| --- | --- | --- |
| 1. | WPV1/VDPV1 |  |
| 2. | WPV2/VDPV2 |  |
| 3. | WPV3/VDPV3 |  |
| 4. | PV nucleic acid |  |

The retention of WPV/VDPV PIM is subject to the approval of the responsible national authority (e.g. MoH) and to the facility’s implementation of containment requirements described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), assessed and certified by the NAC and GCC, following [CCS](http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf).

PV nucleic acid extracted from WPV/VDPV PIM using methods demonstrated to inactivate poliovirus, or synthesized RNA, or complementary DNA (cDNA) can be handled outside of PV containment under the condition that these materials will not be introduced into PV-permissive cells or animals with or without a transfection reagent, except under appropriate containment conditions as described in GAPIII.

# 2. Identification, destruction or retention of OPV/Sabin infectious or potentially infectious material (OPV/Sabin IM or PIM)

## OPV/Sabin infectious material (IM):

**NOTE:** OPV/Sabin IM include OPV vaccines; cell culture isolates and reference strains of these viruses; seed stocks and infectious materials from OPV or Sabin-IPV production; environmental sewage or water samples that have tested positive for the presence of OPV/Sabin strains; faecal or respiratory secretion samples from recent OPV recipients; infected animals or samples from such animals; derivatives that have capsid sequences from OPV/Sabin strains; cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains; as described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/).

Following [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), I conclude that:

The facility **does not** retain any OPV/Sabin **IM**, as follows (please check all that applies):

|  | OPV/Sabin IM | OPV/Sabin IM | | | |
| --- | --- | --- | --- | --- | --- |
|  | Have never been possessed  (tick box if applicable) | Have been destroyed on (please indicate the latest date as dd/mm/yyyy) | Have been inactivated using a method known to inactivate poliovirus on (please indicate the latest date as dd/mm/yyyy | Have been transferred to a PEF on (please indicate the PEF and the latest date as dd/mm/yyyy) |
| 1. | OPV1/Sabin1[[8]](#footnote-8) |  |  |  |  |
| 2. | OPV2/Sabin2[[9]](#footnote-9) |  |  |  |  |
| 3. | OPV3/Sabin3[[10]](#footnote-10) |  |  |  |  |
| 4. | bOPV[[11]](#footnote-11) |  |  |  |  |
| 5. | tOPV[[12]](#footnote-12) |  |  |  |  |
| 6. | mOPV1 |  |  |  |  |
| 7. | mOPV2 |  |  |  |  |
| 8. | mOPV3 |  |  |  |  |
| 9. | PV nucleic acid |  |  | N/A | N/A |

The facility **retains** OPV/Sabin **IM**, as follows:

|  | OPV/Sabin IM | OPV/Sabin IM are retained (please briefly describe the rationale) |
| --- | --- | --- |
| 1. | OPV1/Sabin1 |  |
| 2. | OPV2/Sabin2 |  |
| 3. | OPV3/Sabin3 |  |
| 4. | bOPV |  |
| 5. | tOPV |  |
| 6. | mOPV1 |  |
| 7. | mOPV2 |  |
| 8. | mOPV3 |  |
| 9. | PV nucleic acid |  |

The retention of OPV2/Sabin2 IM is subject to the approval of the responsible national authority (e.g. MoH) and to the facility’s implementation of containment requirements described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), assessed and certified by national containment authorities and GCC, following [CCS](http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf).

PV nucleic acid extracted from OPV/Sabin IM using methods demonstrated to inactivate poliovirus, or synthesized RNA, or complementary DNA (cDNA) can be handled outside of PV containment under the condition that these materials will not be introduced into PV-permissive cells or animals with or without a transfection reagent, except under appropriate containment conditions as described in GAPIII.

In countries that experienced VDPV2 circulation and the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on OPV2/Sabin2 IM will only be completed after the last use of mOPV2.

The collection of data on OPV1/Sabin1 and OPV3/Sabin3 IM has started. However, as the use of bOPV and/or mOPV1/mOPV3 will continue beyond the global eradication of WPV eradication, OPV1/Sabin1 and OPV3/Sabin3 strains are expected to continue to circulate, and the collection of data on OPV1/Sabin1 and OPV3/Sabin3 IM will only be completed after the last use of bOPV and/or mOPV1/mOPV3. The retention of OPV1/Sabin1 IM or OPV3/Sabin3 IM will then be subject to the approval of the responsible national authority (e.g. MoH) and to the facility’s implementation of containment requirements described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), assessed and certified by national containment authorities and GCC, following [CCS](http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf).

## OPV/Sabin potentially infectious material (PIM):

**NOTE:** OPV/Sabin PIM include faecal, respiratory tract, or concentrated sewage samples collected for any purpose in a time and geographic area of OPV use, identified as PIM following the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/); products of such materials from poliovirus permissive cells or animals; respiratory and enteric stocks handled under conditions where OPV/Sabin contamination or replication is possible; as described in [GAPIII](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/).

Following the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/), I conclude that:

The facility **does not** retain OPV/Sabin **PIM**, as follows (please check all that applies):

|  | OPV/Sabin PIM | OPV/Sabin PIM | | | |
| --- | --- | --- | --- | --- | --- |
|  | Have never been possessed  (tick box if applicable) | Have been destroyed on (please indicate the latest date as dd/mm/yyyy) | Have been inactivated using a method known to inactivate poliovirus on (please indicate the latest date as dd/mm/yyyy | Have been transferred to a PEF on (please indicate the PEF and the latest date as dd/mm/yyyy) |
| 1. | OPV1/Sabin1 |  |  |  |  |
| 2. | OPV2/Sabin2[[13]](#footnote-13) |  |  |  |  |
| 3. | OPV3/Sabin3 |  |  |  |  |
| 4. | PV nucleic acid |  |  | N/A | N/A |

The facility **retains** OPV2/Sabin2 **PIM**, as follows (please check all that applies):

|  |  |  |  |
| --- | --- | --- | --- |
| Type of OPV2/Sabin2 PIM | Procedure used with OPV2/Sabin2 PIM | Risk level | Retention (Please describe the rationale) |
| Faecal samples | Inoculation into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Low |  |
| Concentrated sewage | Inoculation into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Low |  |
| Extracted nucleic acid from faecal samples or concentrated sewage | Transfection into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Lowest |  |
| Respiratory tract samples | Inoculation into PV-permissive cells | Low |  |
| Other laboratory procedures | Lowest |  |
| Extracted nucleic acid from respiratory tract samples | Transfection into PV-permissive cells | Low |  |
| Other laboratory procedures | Lowest |  |

Please ensure that complete data on the identification and retention of OPV2/Sabin2 PIM are provided **within 1 year of** the publication of the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/) (i.e. by 10 April 2019).

In countries that experienced VDPV2 circulation and the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on OPV2/Sabin2 PIM will only be completed after the last use of mOPV2.

The retention of OPV2/Sabin2 PIM must be declared to the responsible national authority (e.g. MoH). Recommendations for the safe retention and handling of these materials are provided in the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)*.*

The facility **retains** OPV1/Sabin1 **PIM** or OPV3/Sabin3 **PIM**, as follows (please check all that applies):

|  |  |  |  |
| --- | --- | --- | --- |
| Type of OPV1/Sabin1 PIM or OPV3/Sabin3 PIM | Procedure used with OPV1/Sabin1 PIM or OPV3/Sabin3 PIM | Risk level | Retention  (Please describe the rationale) |
| Faecal samples | Inoculation into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Low |  |
| Concentrated sewage | Inoculation into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Low |  |
| Extracted nucleic acid from faecal samples or concentrated sewage | Transfection into PV-permissive cells | Moderate |  |
| Other laboratory procedures | Lowest |  |
| Respiratory tract samples | Inoculation into PV-permissive cells | Low |  |
| Other laboratory procedures | Lowest |  |
| Extracted nucleic acid from respiratory tract samples | Transfection into PV-permissive cells | Low |  |
| Other laboratory procedures | Lowest |  |

The collection of data on OPV1/Sabin1 and OPV3/Sabin3 PIM has started. However, as the use of bOPV and/or mOPV1/mOPV3 will continue beyond the global eradication of WPV eradication, OPV1/Sabin1 and OPV3/Sabin3 strains are expected to continue to circulate, and the collection of data on OPV1/Sabin1 and OPV3/Sabin3 PIM will only be completed after the last use of bOPV and/or mOPV1/mOPV3.

The retention of OPV1/Sabin1 PIM or OPV3/Sabin3 PIM will then have to be declared to the responsible national authority (e.g. MoH). Recommendations for the safe retention and handling of these materials are provided in the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)*.*

1. *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment* ([CCS](http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf)) [↑](#footnote-ref-1)
2. E.g. data on the retention of OPV1/Sabin1, OPV3/Sabin3 and bOPV will only be collected after the last use of bOPV and mOPV1/mOPV3 [↑](#footnote-ref-2)
3. The collection of data on the identification and retention of WPV1/VDPV1 IM or PIM has started. Please ensure that complete data for WPV1 IM or PIM are provided before the global declaration of WPV eradication. However, as the use of bOPV and/or mOPV1 will continue beyond the global eradication of WPV eradication, VDPV1 are expected to continue to circulate, and the collection of data on VDPV1 IM or PIM will only be completed after the last use of bOPV and/or mOPV1. [↑](#footnote-ref-3)
4. WPV2 was declared eradicated in September 2015. Please provide complete data on the identification and retention of WPV2/VDPV2 IM. In countries that experienced VDPV2 circulation and the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on VDPV2 IM will only be completed after the last use of mOPV2. [↑](#footnote-ref-4)
5. The collection of data on the identification and retention of WPV3/VDPV3 IM or PIM has started. Please ensure that complete data for WPV3 IM or PIM are provided before the global declaration of WPV eradication. However, as the use of bOPV and/or mOPV3 will continue beyond the global eradication of WPV eradication, VDPV3 are expected to continue to circulate, and the collection of data on VDPV3 IM or PIM will only be completed after the last use of bOPV and/or mOPV3. [↑](#footnote-ref-5)
6. 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). [↑](#footnote-ref-6)
7. Please ensure that complete data on the identification and retention of WPV2/VDPV2 PIM are provided **within 1 year of** the publication of the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/) (i.e. by 10 April 2019). In countries that experienced VDPV2 circulation and the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on VDPV2 PIM will only be completed after the last use of mOPV2. [↑](#footnote-ref-7)
8. The collection of data on the identification and retention of OPV1/Sabin1 IM or PIM has started. However, as the use of bOPV and/or mOPV1 will continue beyond the global eradication of WPV eradication, Sabin1 strains are expected to continue to circulate, and the collection of data on OPV1/Sabin1 IM or PIM will only be completed after the last use of bOPV and/or mOPV1. [↑](#footnote-ref-8)
9. Please provide complete data on the identification and retention of OPV2/Sabin2 IM. In countries that experienced OPV2/Sabin2 circulation and/or the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on OPV2/Sabin2 IM will only be completed after the last use of mOPV2. [↑](#footnote-ref-9)
10. The collection of data on the identification and retention of OPV3/Sabin3 IM or PIM has started. However, as the use of bOPV and/or mOPV3 will continue beyond the global eradication of WPV eradication, Sabin3 strains are expected to continue to circulate, and the collection of data on OPV3/Sabin3 IM or PIM will only be completed after the last use of bOPV and/or mOPV3. [↑](#footnote-ref-10)
11. The collection of data on the identification and retention of bOPV has started. However, as the use of bOPV will continue beyond the global eradication of WPV eradication, the collection of data on bOPV will only be completed after the last use of bOPV. [↑](#footnote-ref-11)
12. tOPV is no longer in use. Please provide complete data on the identification and retention of tOPV. [↑](#footnote-ref-12)
13. Please ensure that complete data on the identification and retention of OPV2/Sabin2 PIM are provided **within 1 year of** the publication of the [PIM Guidance](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/) (i.e. by 10 April 2019). In countries that experienced VDPV2 circulation and the use of mOPV2 for outbreak response purposes after the switch from tOPV to bOPV, the collection of data on OPV2/Sabin2 PIM will only be completed after the last use of mOPV2. [↑](#footnote-ref-13)