|  |  |
| --- | --- |
| This document consists of two parts: | Page |
| Section A: Poliovirus Containment Advisory Group (CAG): Terms of Reference and Functions  (updated as of April 2022)……………………………………………………………………………………………………………………..1 | |
| Section B: Template for Submission of Technical Issues on Poliovirus Containment  Implementation to the Poliovirus Containment Advisory Group (CAG) (updated as of July 2022)…………..3 | |

|  |
| --- |
| Section A: Poliovirus Containment Advisory Group (CAG) |

The global strategy for minimizing facility-associated risk of release of poliovirus post-eradication is described in the WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022[[1]](#footnote-1). This is achieved through: risk elimination by destruction of poliovirus materials in all facilities except those designated as serving critical functions e.g., polio vaccine production and control, crucial research, diagnostics, etc. requiring the retention of needed polioviruses post-eradication such as laboratories, vaccine production facilities, etc.; and the biorisk management of facilities retaining polioviruses by compliance with facility-, immunization coverage- and environmental control- safeguards described in GAPIV1. The ‘Biorisk management standard for facilities retaining polioviruses post-eradication’ in GAPIV provides the framework for facility compliance verification and containment certification following the Containment Certification Scheme (CCS)[[2]](#footnote-2). The containment requirements described in GAPIV are in line with other relevant standards and documents[[3]](#footnote-3).

In resolution WHA71.16[[4]](#footnote-4), the World Health Assembly urged all Member States to complete or initiate survey and inventory activities for the relevant polioviruses, reduce to an absolute minimum the number of facilities designated as serving critical functions requiring the retention of needed polioviruses post-eradication, accelerate the progress with national containment certification processes following the CCS, etc.

The Poliovirus Containment Advisory Group (CAG) is an advisory body to the Director-General of WHO and make recommendations on technical issues related to the implementation of the WHO Global Action Plan for Poliovirus Containment, currently GAPIV and other issues associated with poliovirus containment. In this capacity, CAG provides:

* + - 1. Recommendations to WHO and guidance on technical issues arising from implementation of the WHO Global Action Plan for Poliovirus Containment 4th edition, 2022 (GAPIV) and as appropriate, its previous version i.e., WHO Global Action for Poliovirus Containment, 3rd edition, 2015 (GAPIII) during the overall allowable transition period of three years (until: 1 July 2025);
      2. Guidance or recommendations on the containment requirements for the handling of poliovirus-related materials used for purposes of diagnostics, research, polio vaccine production and control, etc [which includes but not limited to the production of virus-like particle (VLP), poliovirus pseudovirus technology, novel oral poliomyelitis vaccine (nOPV), S19 ± N18S-poliovirus strains, PVSRIPO, etc[[5]](#footnote-5).) and other genetically modified poliovirus strains;
      3. Guidance on the identification, risk categorization, destruction and the appropriate containment requirements for the retention and handling of potentially infectious materials, polioviruses and associated tools, etc.;
      4. Guidance on the identification of acceptable alternative measures of compliance with the requirements of GAPIV in the interim period, before certification of WPV eradication.
      5. Oversight function for issues related to poliovirus containment and containment documents e.g., WHO Global Action Plan for Poliovirus Containment, Containment Certification Scheme (CCS), Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance), 2nd edition (2021), etc., including the endorsement of these documents, when needed[[6]](#footnote-6).

Published reports from previous meetings of the Poliovirus Containment Advisory Group (CAG) are available at: <http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>

For any questions or clarifications on the terms of reference of the Poliovirus Containment Advisory Group (CAG), or its functions and responsibilities, please contact: Dr Harpal SINGH [hsingh@who.int](mailto:hsingh@who.int)

|  |
| --- |
| Section B: Template for Submission of Technical Issues on Poliovirus Containment Implementation to the Poliovirus Containment Advisory Group |

|  |
| --- |
| Instruction for use of this template:   1. This template has been developed for the purposes of submission of technical issues related to the implementation of the WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV) and other issues associated with containment implementation to the Poliovirus Containment Advisory Group (CAG). [Please see Section A (Page 1) of this document for the terms of references and relevant technical areas of CAG]. 2. There are six sections to be completed, as appropriate. Please complete the sections with as much information as possible. 3. Please add additional rows to the tables, additional sheets and supporting documents, as needed. 4. This template has been revised in line with the WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV) but may be used for submissions in reference to other containment documents including GAPIII during the overall allowable transition period of three years (until: 1 July 2025), Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance), 2nd edition (2021)[[7]](#footnote-7), etc. 5. Submissions to the Poliovirus Containment Advisory Group (CAG) can be made at any time. 6. Designated facilities intending to provide a submission to CAG, are encouraged to go through their respective National Authority for Containment (NAC), before submission to CAG. 7. For questions on the use of this template, clarifications, any other relevant questions and for the submission of the completed template, please contact: Dr Harpal SINGH [hsingh@who.int](mailto:hsingh@who.int) |

|  |  |  |
| --- | --- | --- |
| Section 1: Document referenced in this submission: (please √ all that apply) | | |
|  | WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV) | |
|  | WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2015 (GAPIII) | |
|  | Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance), 2nd edition (2021) | |
|  | Others: (please specify) |  |
|  |

| Section 2: Name and contact details of person(s) or entity submitting this request | | | | | |
| --- | --- | --- | --- | --- | --- |
| Date of Submission:  YYYY-Month-Day | | | | | |
| Name of sender (Title/First Name/LAST NAME)\* or entity: | | | Email: (institutional or personal ID) | | |
| Position, Department, Institution: | | | | | |
| Street Address: | | | | | |
| City: | State/Province: | Postal Code: | | Country: | |
| Name of the organization(s) consulted and/or supporting the request, if any: | | | | | |
| If this is a joint submission, please indicate the, name(s), email ID, current affiliation and contact details of each member: | | | | | |
|  | | | | | |
| Has the responsible national authority for containment (NAC) reviewed this submission  (only applicable for submissions from designated facilities) | | | | | Yes/No |
| \*Corresponding individual | | | | | |

|  |
| --- |
| Section 3: Summary statement of the request |
| Brief description of the issue, question or proposal being made to CAG: |

|  |
| --- |
| Section 4: Supporting information and justification in line with this request. |
| Relevant section(s) or text(s) of the document e.g., GAPIV, GAPIII, etc. referenced in this submission: |
| Background and contextual Information including justification made in support of this request – all references should be cited. Please include a summary of available supporting data and a list of references used: |
| Any additional information relevant to this submission for CAG deliberation, not already captured elsewhere: (optional) |

|  |
| --- |
| Section 5: Risks associated with the poliovirus materials types and work being performed and the associated proposed alternative measures of compliance with the requirements or the proposed risk mitigation measures. |
| Description of the risk associated with the poliovirus material type and procedure to be used with the said materials. Please include a summary of available supporting data and a list of references used: |
| Description of the proposed alternative measures of compliance with the requirements or the proposed risk mitigation measure(s) including a description of the risk reduction (minimization or elimination) potential of the proposed measures as well as the validation or verification of these measures in addressing the risk identified. Please include a summary of available supporting data and a list of references used: |
| Any additional information relevant to this submission for CAG deliberation, not already captured elsewhere: (optional) |

|  |
| --- |
| Section 6: List of Annexes |
| Annex 1:       (insert title of the annex) |
|  |
| Annex 2:       (insert title of the annex) |
|  |
| Annex 3:       (insert title of the annex) |

The completed template and supporting documentations should submitted via e-mail to: Dr Harpal SINGH [hsingh@who.int](mailto:hsingh@who.int)

Submissions to the Poliovirus Containment Advisory Group (CAG) can be made at any time.

1. WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/> [↑](#footnote-ref-1)
2. Containment Certification Scheme (CCS). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/> [↑](#footnote-ref-2)
3. Such as but not limited to: Containment Certification Scheme (CCS), Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance), 2nd edition (2021), WHO Laboratory Biosafety Manual and Associated Monographs, 4th edition (2020), Guidelines for the safe production and quality control of poliomyelitis vaccines, Annex 4, WHO TRS No 1016 and Annex 3, WHO TRS No 1028 (Amendment to Annex 4 of WHO TRS No 1016), ISO 35001:Biorisk management for laboratories and other related organisations (2019), etc. [↑](#footnote-ref-3)
4. Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – containment of polioviruses (2018). Available at: <https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf> [↑](#footnote-ref-4)
5. S19-poliovirus strains: S19 with the structural (capsid) protein encoding P1-region (of Wild poliovirus or Sabin polioviruses; serotypes 1, 2 or 3); S19/N18S-poliovirus strains: S19 with the structural (capsid) protein encoding P1-region (of Wild poliovirus or Sabin polioviruses; serotypes 1, 2 or 3) with mutation (substitution) of asparagine (N) by serine (S) at amino acid 18 of the non-structural protein 2A for better growth in Vero cells and PVSRIPO: Neuro-attenuated recombinant poliovirus; live attenuated Sabin serotype 1 poliovirus with heterologous internal ribosomal entry site (IRES) of human rhinovirus type 2. [↑](#footnote-ref-5)
6. In 2018, the Strategic Advisory Group of Experts (SAGE) on immunization transferred the oversight function of containment issues and containment-related documents to the Poliovirus Containment Advisory Group. [↑](#footnote-ref-6)
7. A user-friendly digital Potentially Infectious Materials, Poliovirus (PIM) Identification Tool, which is a digital version of the 'Guidance to minimize risks for facilities collecting, handling, or storing materials potentially infectious for polioviruses (PIM Guidance) 2nd edition, 2021' (Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>) has been developed and published. The data source for this tool is based on Web Annex A: Country- and area-specific poliovirus data (Available at: <https://polioeradication.org/pim-guidance-web-annex-a/>) of the PIM Guidance. The digital Potentially Infectious Materials, Poliovirus (PIM) Identification Tool is available at: <https://worldhealthorg.shinyapps.io/pim-app/> . [↑](#footnote-ref-7)