

## GAP CONTAINMENT CERTIFICATION AUDIT REPORT TEMPLATE

**Audit report for** <sup>(1)</sup> <sup>(2)</sup>

Interim Certificate of Containment

Poliovirus Essential Facility (PEF): .....

Assigned PEF Identification: .....

National Authority for Containment (NAC): .....

Audit start date (DD-MM-YYYY): .....

Audit end date (DD-MM-YYYY): .....

GAP standard used for audit (GAP III or GAP IV): .....

**Audit Includes the Following PEF Areas** <sup>(3)</sup>

<b>Area name</b>	<b>Address</b>	<b>Area Activities</b> <sup>(4)</sup>
Area 1		
Area 2		
Area 3		
Area 4		

**Total Number of Non-Conformities (NCs) Identified ELEMENT 1<sup>(5)</sup>**

- 1. Category 1 (Major) Non-conformities (NC1):**
- 2. Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 2<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 3<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 4<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>



**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 5<sup>(5)</sup>**

- 1. Category 1 (Major) Non-conformities (NC1):**
- 2. Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 6<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 7<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 8<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>



**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 9<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 10<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 11<sup>(5)</sup>**

- 1. Category 1 (Major) Non-conformities (NC1):**
- 2. Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 12<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>



**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 13<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 14<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 15<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings:** <sup>(6)</sup>

**Noteworthy Efforts:** <sup>(7)</sup>

**Observations:** <sup>(8)</sup>

**Opportunities for Improvement:** <sup>(9)</sup>

**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

**Total Number of Non-Conformities (NCs) Identified ELEMENT 16<sup>(5)</sup>**

1. **Category 1 (Major) Non-conformities (NC1):**
2. **Category 2 (Minor) Non-conformities (NC2):**

**Key audit findings: <sup>(6)</sup>**

**Noteworthy Efforts: <sup>(7)</sup>**

**Observations: <sup>(8)</sup>**

**Opportunities for Improvement: <sup>(9)</sup>**



**Follow-up Activities Planned:** <sup>(10)</sup>

**Other Attachments:** <sup>(11)</sup>

**Conclusion:** <sup>(12)</sup>

## Directions

- (1) List the name and address of the PEF and the identification number that was assigned at the time of Containment of Participation was approved.
- (2) The NAC may use an introductory letter, or other format, as long as all of the information listed in this template is provided.
- (3) An (area) is defined as a building, room, suite, or other defined space under the management of the PEF where work with poliovirus materials are stored and used. In some PEFs work areas may have different addresses. For example: A university has research laboratories on several campuses located within a metropolitan location. Please note that if there are more than one PEF under the management of a central office but the PEFs are in different metropolitan locations each PEF must apply for containment separately.
- (4) Describe the work that is conducted in the area. For example, manufacturing, research, diagnostic, storage, etc.
- (5) If this report is in support of a CC (All GAP Elements requirements have been met - no non-compliance) provide a list of the non-compliance elements that have been resolved if an application for an ICC was previously submitted.

Definition of NC Category:

### Major (Category 1)

- An absence of one or more required system elements or a situation which raises significant doubt that the activities will be meet specified requirements.
- A group of category 2 non-compliance indicating inadequate implementation or effectiveness of the system relevant to a GAP requirement.
- A category 2 NC that continues to exist without correction as agreed to by the PEF.
- A situation that on the basis of available objective evidence may directly lead to unacceptable risk of breach of containment measures as described in GAP.

### Minor (Category 2)

- The PEF has demonstrated a failure to implement a correction or control implementation of a system/procedural required change but the failure does not indicate a system breakdown or raise concerns that the correction cannot be implemented.
- Despite the non-compliance the overall PEF systems are sufficient to prevent risk of an immediate breach in containment.

A correction action plan (CAP) is required for non-compliance regardless of category. The CAP(s) must be described in the Audit Findings and Corrective Action Plan report. Please refer to this report template for details on the information required.

- (6) Provide a list of all non-compliance findings that are included in the Findings and Corrective Action Report.
- (7) A noteworthy effort is defined as:
  - Adoption of best practices leading to a reduction of risk.
  - Demonstrated improvement in reducing potential risk.
  - Demonstrated level of commitment by the PEF personnel and management to GAP requirements.
  - Enhancements to PEF system that promote a reduction in risk.

- (8) An observation is not a non-compliance but is, in the opinion of the auditors, a situation that has the potential to become a non-compliance if a change is not implemented. It may also be a conclusion that a situation may be non-compliance but there is insufficient evidence to verify that it is a non-compliance.
- (9) An opportunity for improvement relates to areas and/or processes which may meet the minimum requirements of GAP but which could be improved. An opportunity for improvement may be system or performance-related and are recommendations from the auditors based on their knowledge of international best practices and experience of risk mitigation.
- (10) Provide a brief general summary of next actions that will be conducted to move the PEF from an ICC to a CC. If a CC is recommended provide a brief description of actions that will be conducted to monitor the continuing compliance with GAP.
- (11) List any additional documentation that is attached to this report.
- (12) Provide a brief description of the overall assessment of the audit process that was conducted including any concerns or potential future issues that may impact PEF compliance.

## TERMS & CONDITIONS

### Statement of confidentiality

The content of this audit report, including any notes and checklists completed during the audit will be treated in strictest confidence. It will not be disclosed to any third party without written consent of the auditee, except as required by the appropriate authorities.

### Disclaimer

The GAPIII biorisk management system audit is based on verification of a sample of available information at the time of audit. This has an element of uncertainty in the audit findings and in case no non-conformities are identified, it does not mean that they do not exist in the audited and/or other areas.