Note: This form is provided in MS Word .docx format for easier use. Space provided, if insufficient, may be expanded or additional sheets may be added, as needed. Please do not change or alter the questions or clarification requested.

Audit FINDings and CORRECTIVE ACTION PLAN (CAP)

Corrective Action Plan for:

|  |  |
| --- | --- |
| Gap assessment  Initial full-scope ICC audit  ICC Periodic audit (Year 1)  ICC Periodic audit (Year 2) | Initial full-scope CC audit (facilities with ICC against GAPII, applying to CC against GAPIV)  Initial reduced scope CC audit  CC Periodic audit (Year 1)  CC Periodic audit (Year 2)  Recertification audit (CC) |

PEF Organization Information:

Poliovirus-essential Facility (PEF) (1) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National Authority for Containment (NAC) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Audit start date (DD-MM-YYYY) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Audit end date (DD-MM-YYYY) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Conformity (NC): (2)

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| Information to be reflected | |
| Finding No.:  GAPIV Biorisk Management Element No.:  Category:  Immediate Action Required: | 1  1.2.1, 1.2.2, 1.2.3 and 1.2.4  NC1 major  No  Yes |
| Description of NC: (3) | |
| Root Cause Analysis: (4) | |
| Description of Actions Required by PEF to Correct NC: (5) | |
| Description of PEF Plan to Correct NC: | |
| Date Correction of NC to Begin (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Correction of NC is Expected to be Completed (DD-MM-YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Description of NAC Plan to Monitor Correction of NC: | |
| Date PEF NC Correction Verified as Resolved by NAC (DD-MM-YYYY): (6) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Comments: | |

Instructions:

1. Please provide the name of the PEF and the identification number assigned at the time the Certificate of Participation was awarded.
2. Provide separate tables for each non-conformity identified.
3. Describe the requirements in the relevant GAPIV biorisk management element in which the facility was identified to be non-compliant with. Please include the areas impacted by this non-compliance and reasons or justification for classifying the identified non-compliance as NC1 (major) or NC2 (minor). If immediate action is required, please provide a description of the inherent risk of the non-compliance to the personnel, environment or other entities of the facility and its surrounding community.
4. Describe the reasons or causes assessed to have led to the non-compliance identified.
5. If this non-conformity presents as an immediate and severe risk to the personnel, environment or other entities of the facility and its surrounding community, please include the immediate mitigation actions implemented to address and reduce the risk.
6. Complete this after the NC has been resolved and verified by the NAC.