gapiii containment cERTIFICATION

AUDIT REPORt TEMPLATE

Audit report for:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| [ ]  | **Gap assessment** | [ ]  | **Initial audit**  | [ ]  | **Periodic audit** | [ ]  | **Recertification audit** |

Organization:

Audit start date:

Audit end date:

Site Information:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | **Single Site** | [ ]  | **Multisite**  | If so, state no. of sites (excluding HQ): |  |
| Is certification based on site sampling: | [ ]  | **Yes** | [ ]  | **No** |
| **For certification based on site sampling, the lead auditor is required to confirm the following:** |
| The organization meets the following criteria: |
| [ ]  | Centrally controlled common management system |
| [ ]  | Centrally controlled internal audits and management reviews |
| [ ]  | Similarity of activities across sites |
| [ ]  | Key elements of GAPIII are effectively handled by a central office (e.g. management system changes, management review, internal audits, complaints, legal requirements, evaluation of corrective actions and changes in aspects of GAPIII biorisk management system) |
| [ ]  | Full internal audits of all sites have been performed and are proven to be effective (including considerations of relevant regulations) |
| Other comments: |

The audit will cover the following site(s):

|  |  |  |
| --- | --- | --- |
| Site name | Address | Site scope |
| Head office/Main site |  |  |
| Site name 1 |  |  |
| Site name 2 |  |  |
| Site name 3 |  |  |

Modification of scope (if applicable):

Audit team composition:

|  |  |
| --- | --- |
| Role | Name |
| Team leader/lead auditor |  |
| Auditor |  |
| Auditor  |  |
| Expert –  |  |
| Expert –  |  |
| Translator |  |
| Observer |  |

|  |
| --- |
| **Key legal requirements:** |

|  |
| --- |
| **Key outsourced processes:** |

Summary of findings:

Number of Noteworthy Efforts:

Total Number of Non-Conformities (NCs) Identified:

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

Number of Observations:

Key audit findings:

|  |
| --- |
| **Noteworthy efforts:** |

|  |
| --- |
| **Non-Conformities:** |

|  |
| --- |
| **Observations:** |

|  |
| --- |
| **Opportunities for Improvement:** |

Results and conclusion:

**Next Steps:**

To receive the Interim Certificate of Containment/Certificate of Containment, the organization is required to develop a corrective action plan (see the [Audit Findings and Corrective Action Plan](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/#ccsforms)) and submit it to the NAC for review and approval. The development of the CAP shall include the identification of:

* The root cause that led to each NC;
* Corrective actions planned/taken;
* The controls/changes that will be made to ensure that each NC does not recur;
* The timeframe and person responsible for the implementation of the corrective action measure(s);
* The performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

The CAP should be submitted to the relevant NAC within 40 days of receipt of this report.

Next Audit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | **Initial audit**  | [ ]  | **Periodic audit** | [ ]  | **Recertification audit** |

Proposed date:

Other Attachments:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | **Audit plan** | [ ]  | **List of findings** | [ ]  | **Summary of key auditee contacts** |
| [ ]  | **Other (please specify):** |  |

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.

DEFINITION OF FINDINGS

Major (Category 1):

The following NCs should be categorized as major (NC1):

* An absence of one or more required system elements or a situation which raises significant doubt that the activities will meet specified requirements;
* A group of category 2 NCs indicating inadequate implementation or effectiveness of the system relevant to a requirement of GAPIII;
* A category 2 NC that is persistent (or not corrected as agreed by the facility);
* A situation that on the basis of available objective evidence may directly lead to unacceptable risk of breach of containment measures described in GAPIII.

Minor (Category 2):

An NC should be categorized as minor (NC2) when the facility has demonstrated a lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that controls will meet requirements. In this case the judgement is that despite the issues identified, the overall system requirement is defined, implemented and effective.

Noteworthy effort:

A noteworthy effort is described as:

* Adoption of best practices
* Demonstrated improvement
* High level of commitment
* Motivation
* System optimization

Noteworthy efforts should be reported at the closing meeting and in the audit report. They will not enter into the list of findings.

Observation:

An observation is not an NC, but something that could lead to an NC if allowed to continue uncorrected; or an existing condition without adequate supporting evidence to verify that it constitutes an NC.

Opportunity for improvement:

An opportunity for improvement relates to areas and/or processes which may meet the minimum requirements of GAPIII but which could be further improved. An opportunity for improvement may be system or performance-related and is normally addressed based on the experience of the audit team, knowledge of international best practice from other facilities or from practices within other units/departments of the facility.