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 PLAN for initial, periodic or recertification audit for icc or cc

Poliovirus-essential Facility (PEF):

National Authority for Containment (NAC):

Audit start date (DD-MM-YYYY):

Audit end date (DD-MM-YYYY):

|  |  |  |
| --- | --- | --- |
| Unless otherwise indicated, the biorisk management standard used for all activities related to audit activities[[1]](#footnote-1) is GAPIV[[2]](#footnote-2): |  | Check to confirm this audit is to be performed against GAPIV |

Personnel Interviewed:

| Interviewee | | | Auditor Comments |
| --- | --- | --- | --- |
| Acronym | Role/Function | Name of Auditor |
| SM | Senior Management Representative |  |  |
| PI | Principal Investigator/ Production Manager/Lead Scientist |  |  |
| SC | Safety Committee Chairman |  |  |
| HR | Human Resources Manager |  |  |
| SO | Security Officer |  |  |
| FO | Facility Officer |  |  |
| OH | Occupational Health Doctor/Nurse |  |  |
| BSO | Biosafety Officer |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Add additional rows as needed | | | |

| Audit Plan Sample (Biorisk management elements indicated in this sample audit plan has been updated to be in line with the terminology used in GAPIV) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Day | Team 1 | Interviewees | Team 1 members | Team 2 | Interviewees | Team 2 members |
| Monday |  |  |  |  |  |  |
| 0900 - 0930 | Opening meeting | Management and All Involved | All |  |  |  |
| 0930 - 1200 | Document review, orientation and site tour |  |  |  |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1600 | Biorisk Management System |  |  |  |  |  |
| 1630 - 1700 | Summary and review |  |  |  |  |  |
| Tuesday |  |  |  |  |  |  |
| 0900 - 1200 | Risk Assessment and Control |  |  | Good Microbiological Practice and Procedures |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1430 | Waste Management, Decontamination, Disinfection and Sterilization |  |  | Poliovirus Inventory and Information |  |  |
| 1430 – 1600 | Clothing and PPE |  |  | Emergency Response and Contingency Planning |  |  |
| Wednesday |  |  |  |  |  |  |
| 0900 – 1030 | Competency and Training |  |  | Transport Procedures |  |  |
| 1030 – 1200 | Workers Health Programme |  |  | Security |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1430 | Equipment and Maintenance |  |  |  |  |  |
| 1430 - 1600 | Facility Physical Requirements |  |  |  |  |  |
| 1630 - 1700 | Summary and review |  |  |  |  |  |
| Thursday |  |  |  |  |  |  |
| 0900 - 1200 | Facility visits |  |  | Facility visits |  |  |
| 1300 - 1600 | Facility visits |  |  | Facility visits |  |  |
| Friday |  |  |  |  |  |  |
| 0900 - 1200 | Verifications / presentation preparation |  |  |  |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1400 | Close-out Presentation | Management and All Involved |  |  |  |  |

1. From 1 January 2024, all audits must be performed against GAPIV [↑](#footnote-ref-1)
2. WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV). Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf> and WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2014 (GAPIII). Available at: <http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf> [↑](#footnote-ref-2)