FORM APPROVED
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EXP DATE: xx/xx/20xx

NAC
U.S. National Authority
for Containment of Poliovirus

Global Action Plan (GAP) Poliovirus Containment Poliovirus- Essential Facility Assessment Checklist

The Poliovirus-Essential Facility (PEF) Assessment Checklist is used to aid facilities preparing for an audit to obtain a poliovirus (PV) containment certification. Facility information for U.S. laboratories retaining PV materials will be maintained by the U.S. NAC but may be shared upon request with regional and international health authorities (Pan American Health Organization (PAHO), World Health Organization (WHO)) as relevant to WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication. Note that as of May 2022, wild PV type 1 (WPV1) and type 3 (WPV3) infectious materials used or stored in containment areas must be included.

Your facility has submitted a Certificate of Participation to the U.S. National Authority for Containment (NAC) of Poliovirus and committed to containment of poliovirus (PV) materials in accordance with the WHO Containment Certification Scheme (CCS). Poliovirus containment certification in the United States is a multi-step process overseen by the U.S. NAC.

Contents

SECTION 1: FACILITY DOCUMENTS

Facility documents used for the development of an audit plan.

Document	Align to GAP Requirements (Yes / In Progress / No)
An organizational chart outlining the Biorisk management-related roles and responsibilities.	
Biorisk management related documents (policies) and records.	
A register of applicable laws, standards, and guidelines.	
Biosafety/Biosecurity manuals and associated procedures.	
Accident/Incident records relevant to poliovirus containment.	
The list of contracted services, companies, and individuals.	
Risk Assessments (e.g., those relating to emergency preparedness, procedural controls, the design and operation of the facility and equipment, decontamination measures, security measures, and maintenance).	
A map/floor plan, including any relevant support areas (e.g., ventilation areas, effluent treatment plant, storage areas, waste handling/storage locations).	

SECTION 2: FACILITY INFORMATION

1. Facility Assessment Completion Date: _____

2. Containment certificate(s) desired (Check all that apply):

Interim Certificate of Containment (ICC) ☐ Certificate of Containment (CC) ☐

3. Facility Name: _____

4. Office/Dept.: _____

5. Facility Physical Address: _____

6. Additional Offsite Address: _____

7. Individuals with key roles in the GAP biorisk management system have been designated as follows:

Role	Name
Senior manager	
Biorisk management advisor (e.g., BSO)	
Scientific manager (e.g., PI)	
Occupational health professional	
Facility manager	
Security manager	

Role	Name
Animal care manager (if applicable)	
Laboratory representative	
Quality manager	
Emergency response manager	

SECTION 3: FACILITY ASSESSMENT QUESTIONAIRE

The following checklist reports PEF progress for GAP containment to assist the facility in preparation for a future NAC audit. In addition, the completed questionnaire will be requested by the NAC to assist in developing an audit plan and determining readiness for Stage 1 audit. For each question below, please indicate "yes" or "no" to report the PEF's status on GAP and US NAC policy topics. If the topic is anticipated to be an ICC-NC, please indicate "no". Provide any additional information in the remarks section.

Element 1 - Biorisk Management System

		Y	N	Remarks
1.	Does your facility have an internal audit process?			
	1a. Has an internal audit for GAP been completed? If so, please add the date in the Remarks column.			
2.	Does the facility have a system to capture audit non-conformances?			
3.	Are there preventative primary safeguards (i.e., facility management, facility design and construction, and immunization of personnel) in place to reduce the likelihood of the release of poliovirus material?			
4.	Is the Biorisk management system reviewed at a predefined frequency (e.g., biannually) to ensure suitability, adequacy, and effectiveness?			
5.	Are key performance indicators (i.e., audits and incident reporting) in place to monitor the biorisk management system?			
6.	Does the facility have a document control system in place?			
	6a. Are controls in place for the review, update, and reapproval of documents?			
7.	Is a communication system defined to ensure relevant and current information that can potentially affect staff and others? Is the communication system and its delivery to relevant personnel effective?			
8.	Are the processes for selection and evaluation of suppliers/contractors aligned with GAP?			
9.	Are continual improvement processes in place for various elements in GAP?			
10.	Is general safety included in the GAP biorisk management system?			
11.	Is there change management process in place and is it documented?			

Element 2 - Risk Assessment and Control

		Y	N	Remarks
1.	Is there general safety training for physical hazards associated with the work in the facility? (e.g., general laboratory safety, chemical, and fire safety)			
2.	Is there a hazard plan in place?			
3.	Are biological hazards identified and assessed in relation to the potential dangers to humans and the environment?			
4.	Is there a risk management system established in the facility?			
	4a. Has the system been aligned to GAP with personnel responsible and accountable for the implementation?			
	4b. Is compliance with the risk management system reviewed at least annually?			
5.	Has the facility conducted a risk assessment for GAP derogations?			
	5a. Are risk assessments for GAP derogations peer- reviewed?			
6.	Has the facility defined the process used to identify the need for a new risk assessment or the need to review an existing one?			

Element 3 - Worker Health Program

		Y	N	Remarks
1.	Does the facility ensure that the risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively, including through preventive and protective measures?			
2.	Has a vaccination policy been defined and implemented based on risk and exposure?			
3.	Does the facility verify immunization and poliovirus protective immunity for essential personnel?			
4.	Does the facility verify immunization records for support staff, visitors, and contractors that enter poliovirus containment area?			
5.	Has the facility established a system to effectively manage medical and/or environmental emergencies, including but not limited to identifying potentially infected workers and providing immediate medical care to exposed, ill or injured workers?			
6.	Has the facility implemented the U.S. NAC Policy for Occupational Health Programs at U.S. Poliovirus-essential facilities?			

Element 4 - Competence and Training

		Y	N	Remarks
1.	Are qualifications, experience and aptitudes related to biorisk considered as part of the employee recruitment process?			
	1a. Has the process been aligned with GAP requirements/and or guidance?			
2.	Are the requirements and procedures for biorisk-related training of personnel identified, established, documented, and maintained?			
3.	Have competency levels been defined and documented for staff?			
	3a. Are records maintained to show staff members have obtained and demonstrated required levels of competency?			
4.	Does the facility have a process to identify roles and individuals that require a back-up ensuring the integrity of the facility is not compromised through short- or long-term absence?			
5.	Are there measures put in place for personnel who are no longer employed at the facility (e.g., remove access to the facility, computerized records, and data)?			
6.	Does the facility have an established program to address risk associated with human behavior, as it pertains to health and safety, including the management of how workers interact with the facility and its equipment?			
	6a. Has the program been aligned to the GAP biorisk management system?			
7.	Has the program implemented a Personnel Reliability Program as outlined in the U.S. NAC *Policy for U.S. Poliovirus-essential facilities to Control Security of Poliovirus Materials and Information*?			

Element 5 - Good Microbiological Practice and Procedure

		Y	N	Remarks
1.	Is a site-specific biosafety manual in place? (Based on risk assessments focused on hazards associated with poliovirus/poliovirus containing materials)			
2.	Are appropriate resources (including time and equipment) available to ensure good microbiological techniques are implemented and effective?			
3.	Is training in good microbiological techniques provided (i.e., annually, biannually)?			

Element 6 - Clothing and Personal Protective Equipment (PPE)

		Y	N	Remarks
1.	Was adequate information used in selecting PPE (e.g. risk assessments, review and analysis of tasks and employee feedback)			
2.	Are containment areas labeled with the appropriate level of PPE required?			
3.	Is suitable equipment made available, used, and maintained appropriately within the facility?			

Element 7 - Security

		Y	N	Remarks
1.	Are controls in place for the physical security of cultures, specimens, samples and potentially contaminated materials or waste, determined as part of the risk assessment process?			
2.	Are policy and procedures in place to identify sensitive information?			
3.	Does the facility have a process in place to ensure that suppliers, contractors, visitors, and subcontractors adhere to the established management systems' requirements and do not compromise the facility's biorisk management?			
	3a. Is the process documented and reviewed periodically?			
4.	Has the program implemented poliovirus material and information security measures as outlined in the U.S. NAC *Policy for U.S. Poliovirus-essential facilities to Control Security of Poliovirus Materials and Information*?			

Element 8 - Facility Physical Requirements

		Y	N	Remarks
1.	Is there a formal process to commission new facilities and decommission existing facilities?			
2.	Does the facility design process identify and incorporate all relevant legislative requirements, recognized standards, guidelines, industry good practices and facility-specific risk assessments?			
3.	Does the poliovirus containment area meet current GAP physical feature requirements? (excluding any final containment requirements at this time)			

Element 9 - Equipment and Maintenance

		Y	N	Remarks
1.	Is a maintenance program for the poliovirus-essential facility and equipment documented and aligned to GAP?			
2.	Are equipment control procedures documented and aligned to GAP? (e.g., equipment inventory and calibration)			
3.	Does the facility ensure calibration and certification is scheduled and conducted as required by the manufacturer's requirements and/or at other specified intervals as identified by risk assessments?			
4.	Does the facility ensure competent and independent process mechanisms are used when validating equipment?			

Element 10 - Poliovirus Inventory and Information

		Y	N	Remarks
1.	Does the facility have a risk assessed based inventory process with controls in place?			
	1a. Has the poliovirus inventory management system been aligned to the U.S. NAC *Policy for Poliovirus-Essential Facilities to Manage Inventory*?			
2.	Is there a documented process for intra-facility and inter-facility transfers of poliovirus?			
3.	Has the facility conducted an inventory audit?			
	3a. Are the physical inventory and associated records reviewed at least annually?			
4.	Is the storage area equipped with back-up emergency power source and with recording alarms systems to monitor freezers?			

Element 11 - Waste Management, Decontamination, Disinfection and Sterilization

		Y	N	Remarks
1.	Does the facility have an established program for appropriate waste management for poliovirus materials?			
	1a. Has the facility identified and documented all contaminated or potentially contaminated waste streams?			
2.	Are SOPs validated and shown to be effective against poliovirus prior to their use?			
3.	Have inactivation protocols been validated in accordance with the NAC *Policy for U.S. Facilities to Inactivate Poliovirus* Materials?			

Element 12 - Transport Procedures

		Y	N	Remarks
1.	Does the facility have an established program for transfers and transport of poliovirus, both inside and outside the facility containment perimeter?			
	1a. Are transfers documented?			
2.	Does the facility report poliovirus material transfers to US NAC consistent with NAC *Policy for U.S. Facilities to Transfer Poliovirus Materials*?			

Element 13 - Emergency Response and Contingency Planning

		Y	N	Remarks
1.	Does the facility have a risk assessed based emergency plan in place and are biological risks considered?			
2.	In the event of an emergency, are adequate contingency measures in place to ensure the safety and security of continued operations?			
3.	Are emergency plans effectively communicated to all employees and relevant third parties, and tested with the goal of making everyone aware of their obligations?			
4.	Has the facility implemented the U.S. NAC *Policy for Emergency Response and Exposure Management Plans at U.S. Poliovirus-essential facilities*?			
	4a. Have PV-specific drills and exercises been conducted?			

Element 14 - Accident/Incident Investigation

		Y	N	Remarks
1.	Has facility defined criteria for what constitutes a significant poliovirus exposure?			
	1a. Has a poliovirus post-exposure response plan been established?			
2.	Are personnel responsible for maintaining the accident/incident reporting system been identified?			
3.	Are documented procedures established and maintained to define, record, analyze and learn from accidents and incidents involving poliovirus?			

SECTION 4: FACILITY EVALUATION CHART

The following table provides a summary of progress for GAP containment. This information will assist the NAC in developing an audit plan and determining readiness for a Stage 1 certification audit.

Element	Documented *(Yes or No)*	Monitored *(Yes or No)*	Element	Documented *(Yes or No)*	Monitored *(Yes or No)*
Element 1 Biorisk Management System			**Element 8** Facility Physical Requirements		
Element 2 Risk Assessment and Control			**Element 9** Equipment and Maintenance		
Element 3 Worker Health Program			**Element 10** Poliovirus Inventory and Information		
Element 4 Competence and Training			**Element 11** Waste Management, Decontamination, Disinfection and Sterilization		
Element 5 Good Microbiological Practice and Procedure			**Element 12** Transport Procedures		
Element 6 Clothing and Personal Protective Equipment			**Element 13** Emergency Response and Contingency Planning		
Element 7 Security			**Element 14** Accident and Incident Investigation		

Declaration of Validity

I hereby declare that to the best of my knowledge the information contained within this questionnaire is true and accurate. I understand that the information may be used in the evaluation process to assess the named organization's suitability as a Poliovirus-Essential Facility

Signature: _____
Principal Investigator

Signature: _____
Completed By

Completed By: Date:

Job Position:

Telephone: