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 REPORt

This audit report should be filled out for initial and periodic audits, audits for upgrades from ICC to CC, and audits for ICC or CC recertification. This audit report may be used for both full-scope and reduced-scope audits. If reporting on a reduced-scope audit, please indicate which elements were not audited and a rationale for this decision rather than leaving them blank.

Audit report for (1) (2)

[ ]  Interim Certificate of Containment [ ]  Certificate of Containment

Poliovirus-essential Facility (PEF):

PEF address:

National Authority for Containment (NAC):

Audit start date (DD-MM-YYYY):

Audit end date (DD-MM-YYYY):

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| Unless otherwise indicated, the biorisk management standard used for all relevant audit activities[[1]](#footnote-1) is GAPIV[[2]](#footnote-2): (Please check the box to confirm which published version of GAPIV the audit was conducted against) | [ ]  GAPIV (2022) | [ ] GAPIV (2025) |

For the following section, please clearly describe the area location relative to the rest of the facility and indicate the specific activities taking place in each area. This section is designed to give the GCC-CWG a clear understanding of the sites or areas where polioviruses are stored or handled and how the facility operates as a whole. Inclusion of a site map which identifies areas where polioviruses are stored or handled with this audit report is strongly encouraged. Ensure any abbreviations used are written in full in parentheses following their first use in this document. The audit performed included the following sites or areas of this facility(3):

|  |  |
| --- | --- |
| Site or Area name | Area Activities(3)  |
| Area 1 | a)b)c)… |
| Area 2 | a)b)c)… |
| Area 3 | a)b)c)…*(Please add additional rows as needed)* |

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| Audit Findings Summary |

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| Total number of findings identified across all elements (including observations):  |

Breakdown of findings

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| --- | --- | --- | --- |
| Type of finding | Abbreviation | Number of findings in category | Relevant GAPIV element and sub-element |
| Category 1 (Major) \* | NC1 |  |  |
| Category 2 (Minor)\* | NC2 |  |  |
| Nonconformities under an ICC (Major) | ICC-NC |  |  |
| Observation | N/A |  |  |
| Noteworthy efforts | N/A |  |  |
| GAPIV elements for which no nonconformities or observations were identified during the audit: |

#### \*An NC should be categorized as major (NC1) when there is:

* an absence of one or more required system elements, or a situation that raises significant doubt that the activities will meet the specified requirements;
* a group of Category 2 NCs indicating inadequate implementation or effectiveness of the system relevant to one of the standard’s requirements;
* a Category 2 NC that is persistent (or not corrected as agreed by the facility), thus upgraded to Category 1; and/or
* a situation that on the basis of available objective evidence may directly lead to an unacceptable risk of breach of containment measures described in GAPIV.

### An NC should be categorized as minor (NC2) when a facility’s demonstrated lapse of discipline or control during the implementation of system/ procedural requirements does not indicate a system breakdown or raise significant doubt that controls will meet the specified requirements. In this case the judgement can be that, despite the issues identified, the overall system requirement is defined, implemented and effective. However, they may be instances when several NC2 may collectively lead to an unacceptable risk of breach in containment.

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| Biorisk Management Element 1 – Biorisk Management System |

Total Number of Non-Conformities (NCs) Identified ELEMENT 1(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 2 – Risk Assessment and Control |

Total Number of Non-Conformities (NCs) Identified ELEMENT 2(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 3 – Worker Health Programme |

Total Number of Non-Conformities (NCs) Identified ELEMENT 3(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 4 – Competence and Training |

Total Number of Non-Conformities (NCs) Identified ELEMENT 4(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 5 – Good Microbiological Practice and Procedure |

Total Number of Non-Conformities (NCs) Identified ELEMENT 5(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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| Biorisk Management Element 6 – Clothing and Personal Protective Equipment (PPE)  |

Total Number of Non-Conformities (NCs) Identified ELEMENT 6(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 7 – Security |

Total Number of Non-Conformities (NCs) Identified ELEMENT 7(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 8 – Facility Physical Requirements |

Total Number of Non-Conformities (NCs) Identified ELEMENT 8(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 9 – Equipment and Maintenance |

Total Number of Non-Conformities (NCs) Identified ELEMENT 9(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 10 – Poliovirus Inventory and Information |

Total Number of Non-Conformities (NCs) Identified ELEMENT 10(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 11 – Waste Management, Decontamination, Disinfection and Sterilization |

Total Number of Non-Conformities (NCs) Identified ELEMENT 11(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 12 – Transport Procedures |

Total Number of Non-Conformities (NCs) Identified ELEMENT 12(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 13 – Emergency Response and Contingency Planning |

Total Number of Non-Conformities (NCs) Identified ELEMENT 13(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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| Biorisk Management Element 14 – Accident/Incident Investigation |

Total Number of Non-Conformities (NCs) Identified ELEMENT 14(5)

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|  | Category of Nonconformity (NC)  | Abbreviation  | Total Number Identified |
|  | Category 1 (Major) | NC1 |  |
|  | Category 2 (Minor) | NC2 |  |
|  | Nonconformities under an ICC (Major) *(only applicable under an ICC)* | ICC – NC  |  |

Key audit findings: (6)

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Noteworthy Efforts: (7)

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Observations: (8)

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Follow-up Activities Planned:

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Other Attachments: (9)

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Conclusion: (10)

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Instructions:

1. List the name and address of the PEF and the identification number assigned at the time the Certificate of Participation was awarded.
2. NACs may utilize an introductory letter, or another suitable format, provided all of the information listed within this template is available.
3. An area is defined as a building, room, suite, or other defined space under the management of the PEF where poliovirus materials are stored or handled. In some PEFs work areas may have different addresses. For example: A university may have research laboratories in several campuses located within the same metropolitan area. Containment certification applications of PEFs under a single institutional management located in different metropolitan should be made separately.
4. Describe all work conducted in the said areas e.g., vaccine production, research, diagnostic, storage, etc.
5. 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.

ICC – NC

* An NC that cannot be closed due to the need for major structural work or for other reasons and are by definition NC1s (major) since they represent an absence of one or more required system elements.

A correction action is required for non-compliance regardless of category. The corrective action and other relevant details and information must be described in the Audit Findings and Corrective Action Plan template.

1. Provide a list of all non-compliances that are to be included in the Audit Findings and Corrective Action Plan template.
2. 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 GAPIV requirements.
* Enhancements to PEF system that promote a reduction in risk.
1. 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.
2. List additional documentation attached to this report.
3. 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 the compliance of the PEF with the requirements in GAPIV.

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.

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>

3The GCC-CWG requests a detailed description of all activities conducted in the indicated area [↑](#footnote-ref-2)